WTO – GATT SPS AND TBT

SCHOOL ON TRADE AND PUBLIC HEALTH
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GENESIS OF THE MULTILATERAL TRADING SYSTEM

- In 1944, Bretton Woods Conference (United Nations Monetary and Financial Conference) was convened to discuss
  - Post-war recovery of Europe
  - Monetary issues, such as unstable exchange rates and protectionist trade policies
- Delegates from 44 countries discussed the establishment of
  - International Trade Organization (ITO)
  - International Bank for Reconstruction and Development
  - International Monetary Fund

GATT 1947 - THE ORIGIN

- **In anticipation of Havana Charter to be adopted in 1948, the GATT was adopted in 1947 by the Contracting Parties. Havana Charter failed as USA did not ratify.**

- **General Agreement on Tariffs and Trade, 1947**
  - ***Entered into force: 1 January 1948***
  - ***Terminated: 31 December 1995, but substance lives on as GATT 1994***

- **"Original" 23 contracting parties, including India, agreed on substantial tariff reductions**

MOTIVATIONS FOR ESTABLISHING MULTILATERAL TRADING SYSTEM

- Phased opening of markets by reducing/removing all forms of trade barriers
- Rules-based system to curb tendencies of unilateral action by larger trading countries
- Transparency in the making of global trading rules
- Predictability in the setting of trade rules provides ideal environment for business to operate

RESULTS OF THE URUGUAY ROUND

The Legal Texts - a daunting list of about 60 agreements, annexes, decisions and understandings. In fact, the agreements fall into a simple structure with six main parts:

- **an umbrella agreement (the Agreement Establishing the WTO);**
- **agreements for each of the three broad areas of trade that the WTO covers (goods, services and intellectual property);**
- **dispute settlement;**
- **and reviews of governments' trade policies.**

WORLD TRADE ORGANISATION

- Location: Geneva, Switzerland
- Established: 1 January 1995
- Created by: Uruguay Round negotiations (1986–94)
- Membership: 153 countries (September 2009)
- Secretariat staff: 630
- Head: Pascal Lamy (Director-General)

Functions:

- Administering WTO trade agreements
- Forum for trade negotiations
- Handling trade disputes
- Monitoring national trade policies
- Technical assistance and training for developing countries
- Cooperation with other international organizations

BASIC GATT PRINCIPLES

- MFN (Most Favoured Nation Treatment)
- TRADE TO BE REGULATED BY CUSTOMS DUTY ONLY
- DUTIES TO BE BOUND
- NATIONAL TREATMENT

ADDITIONAL DETAILS

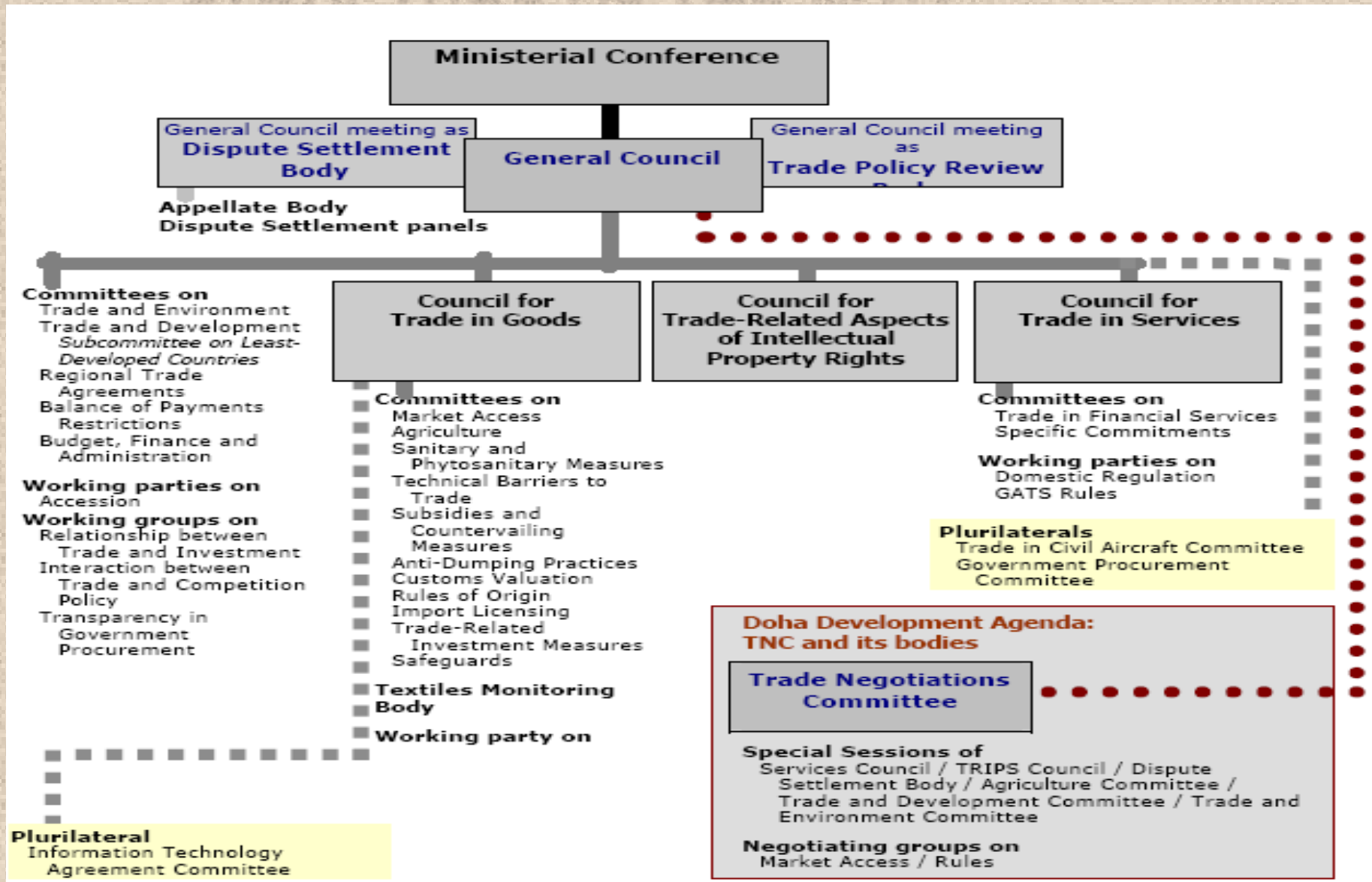
These agreements and annexes deal with the following specific sectors or issues:

- For goods (under GATT)
  - Agriculture
  - Health regulations for farm products (SPS)
  - Textiles and clothing
  - Product standards (TBT)
  - Investment measures
  - Anti-dumping measures
  - Customs valuation methods
  - Pre-shipment inspection
  - Rules of origin
  - Import licensing
  - Subsidies and counter-measures
  - Safeguards
- For services (the GATS annexes)
  - Movement of natural persons
  - Air transport
  - Financial services
  - Shipping
  - Telecommunications

WTO MINISTERIALS

- Singapore, 9-13 December 1996
- Geneva, 18-20 May 1998
- Seattle, November 30 – December 3, 1999
- Doha, 9-13 November 2001
- Cancún, 10-14 September 2003
- Hong Kong, 13-18 December 2005
- Geneva, 30 November - 2 December 2009

STRUCTURE OF THE WTO



WTO AND PUBLIC HEALTH

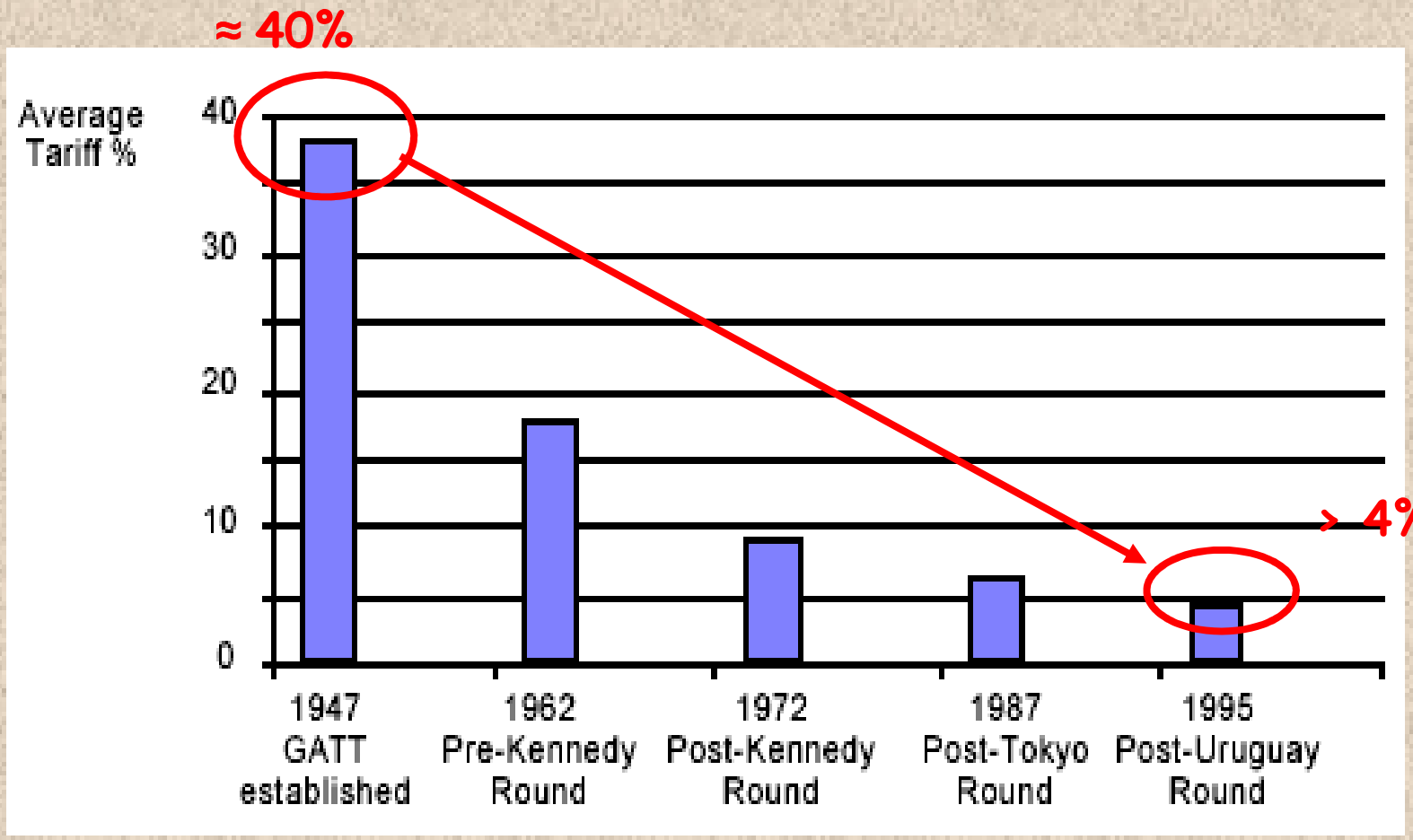
Objectives of WTO:

"Recognizing that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development, …" [emphasis added]

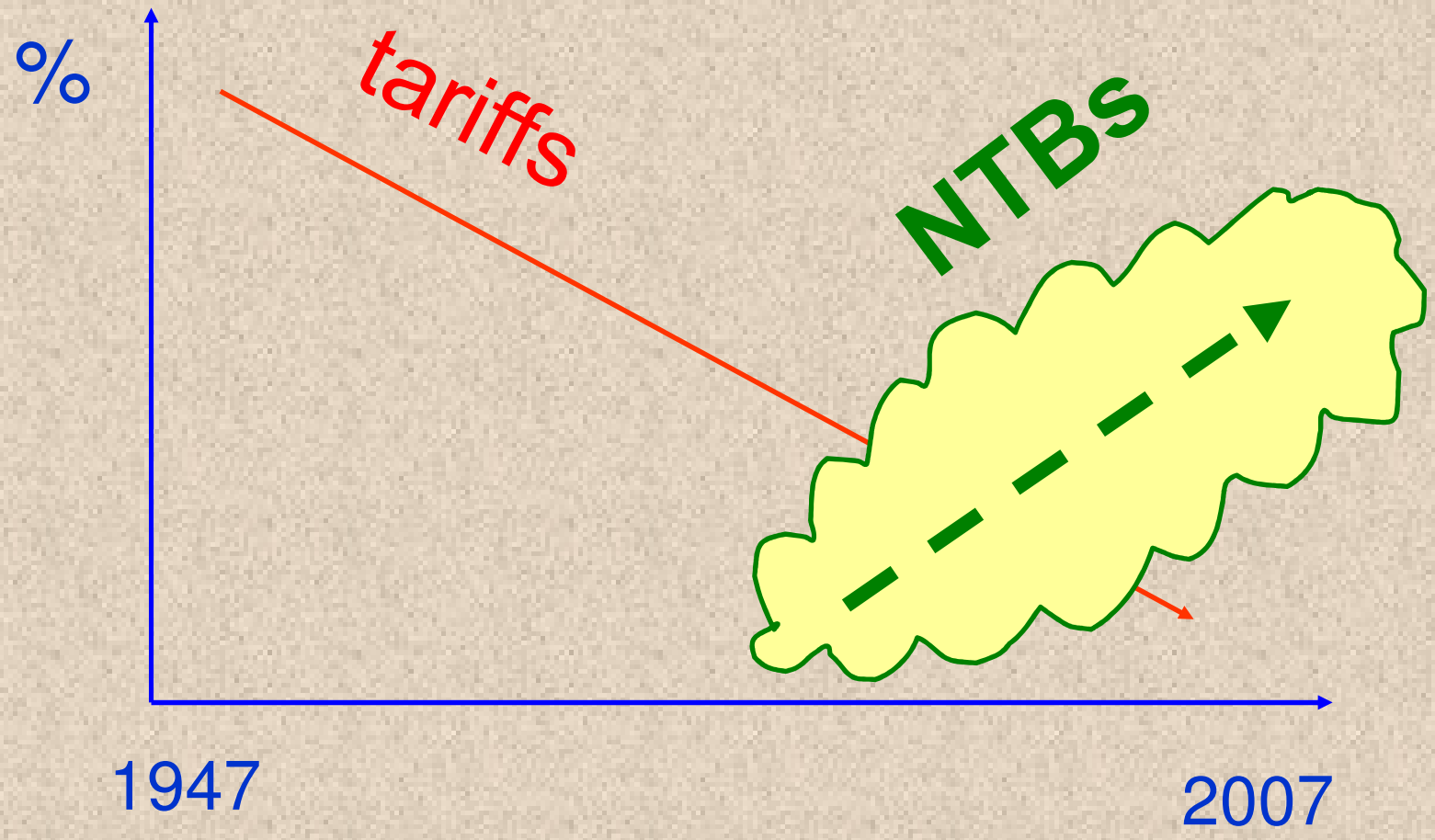
STANDARDS AND SAFETY

- Article XX of the General Agreement on Tariffs and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism.
- In addition, there are two specific WTO agreements dealing with food safety and animal and plant health and safety, and with product standards in general. Both try to identify how to meet the need to apply standards and at the same time avoid protectionism in disguise:
  - The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
  - Agreement on Technical Barriers to Trade (TBT Agreement.)

Overall, import weighted tariff on industrial products

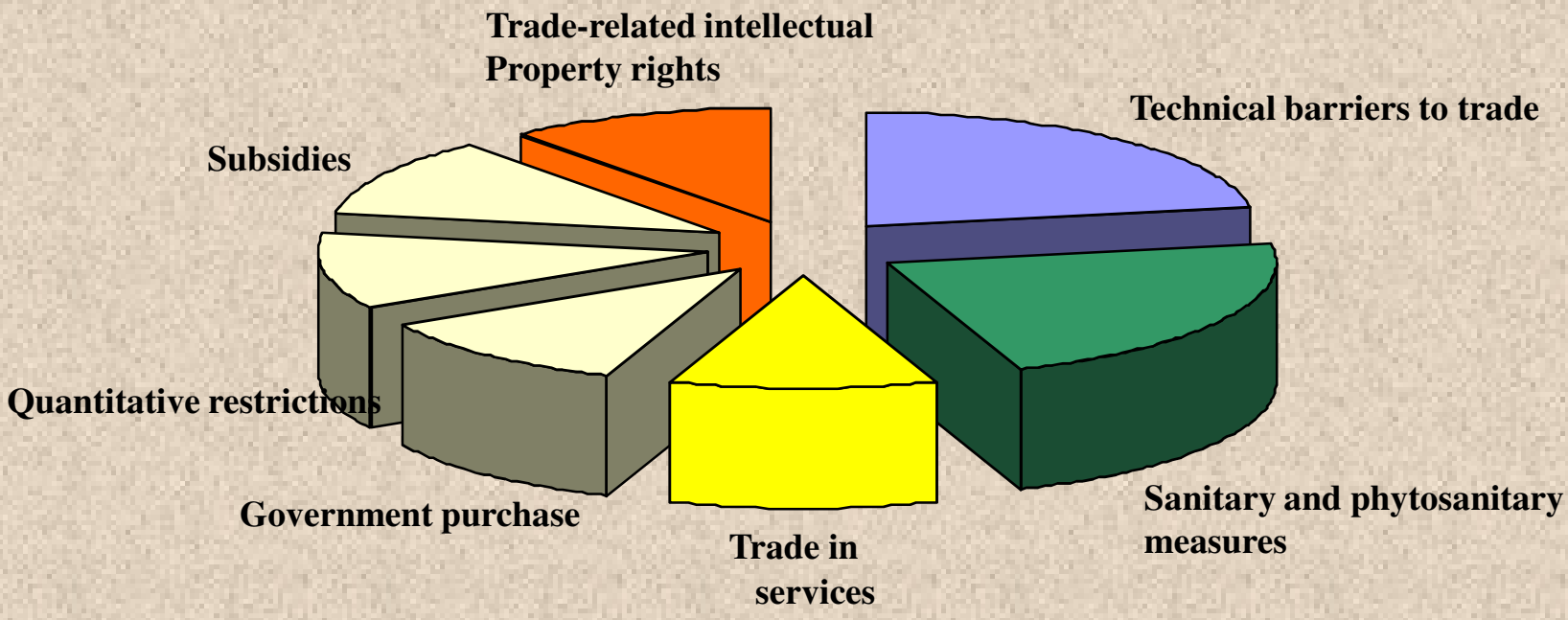


Source: WTO



Source: WTO

NON-TARIFF MEASURES



OBJECTIVE OF THE TBT AGREEMENT

Recognizes

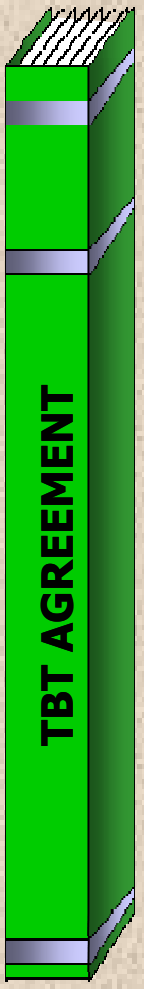
That no country should be prevented from taking measures (technical regulations, standards, conformity assessment procedures)

Ensures

That such measures do not create unnecessary obstacles to trade

TBT AGREEMENT: THE COVERAGE

Art. 1.3

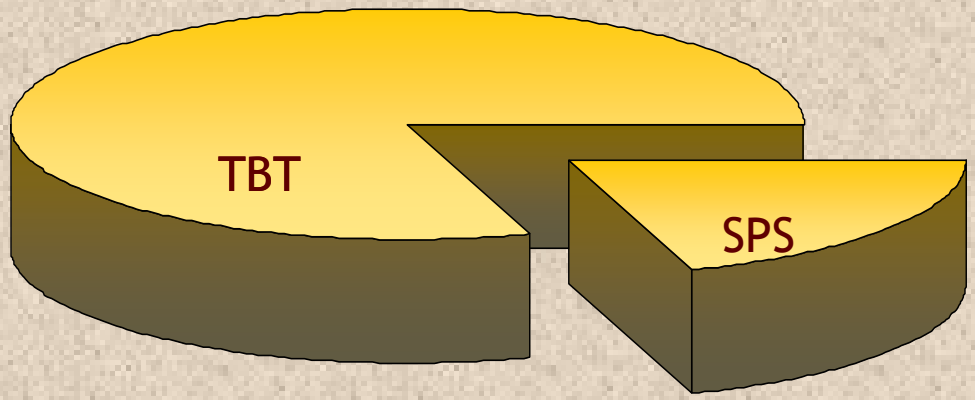


"All products, including industrial and agricultural products, shall be subject to the provisions of this Agreement."

THE TBT AGREEMENT

It applies to all

- **+ technical regulations (mandatory)**
- **+ standards (voluntary)**
- **+ conformity assessment procedures**



But: its provisions do not apply to SPS measures

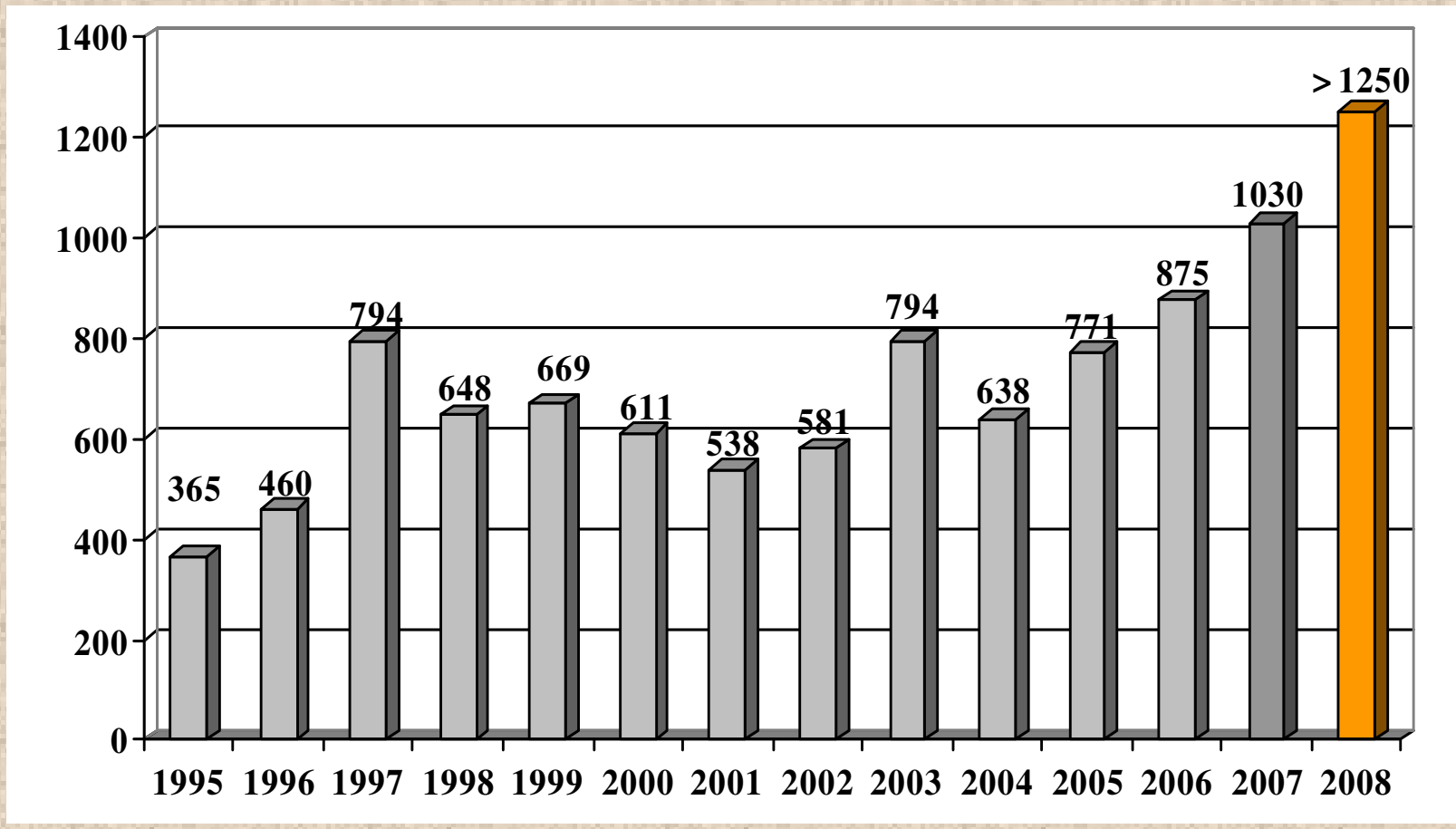
The TBT Agreement does not cover

Sanitary and Phytosanitary measures

Services

Purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies

TBT NOTIFICATIONS SINCE 1995



Source: WTO

What is the purpose of the SPS Agreement?

The right to protect human, animal or plant life or health

Avoiding unnecessary barriers to trade

SPS Agreement - Basic Right

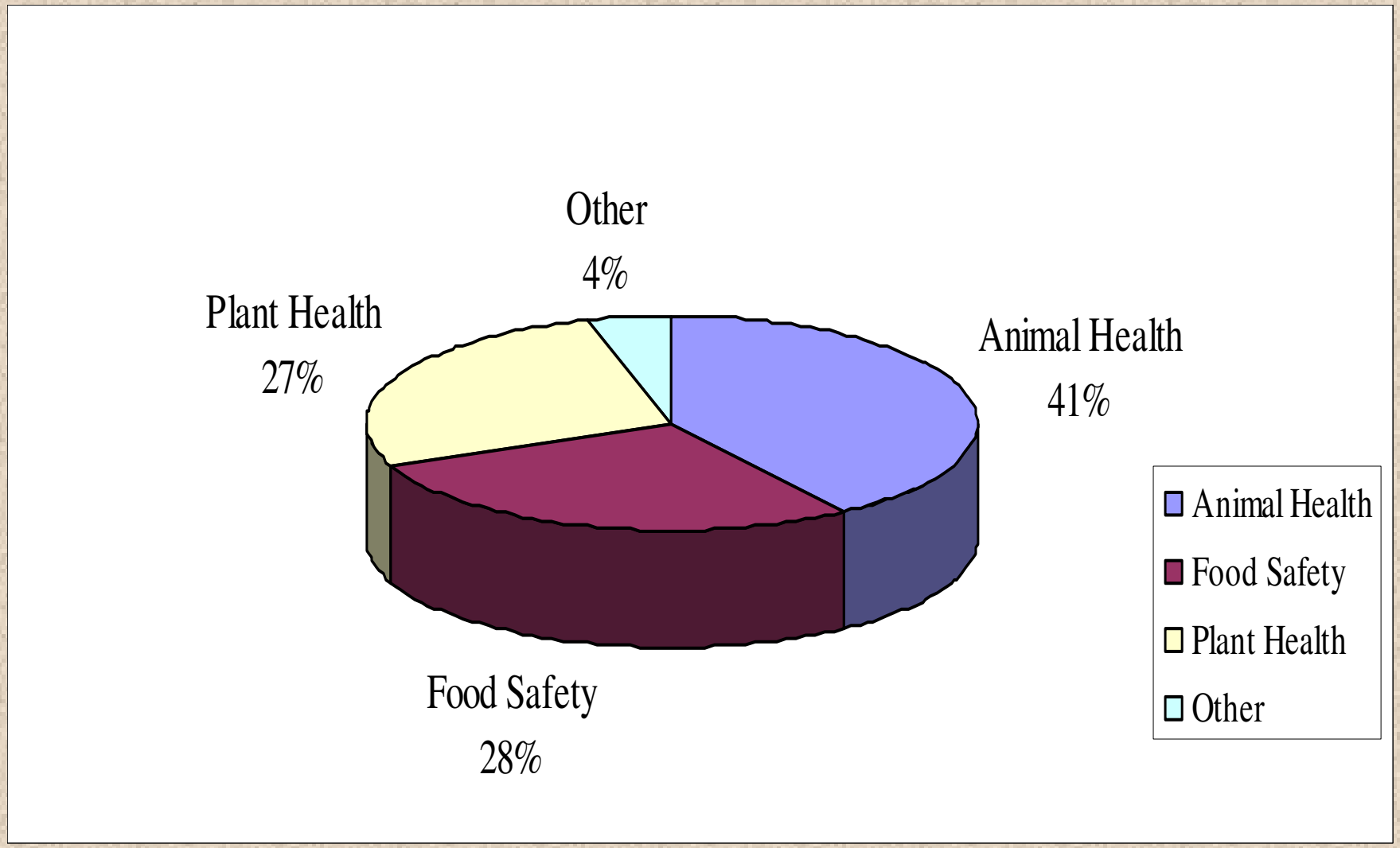
"Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement"

SPS MEASURES

A measure taken to protect:

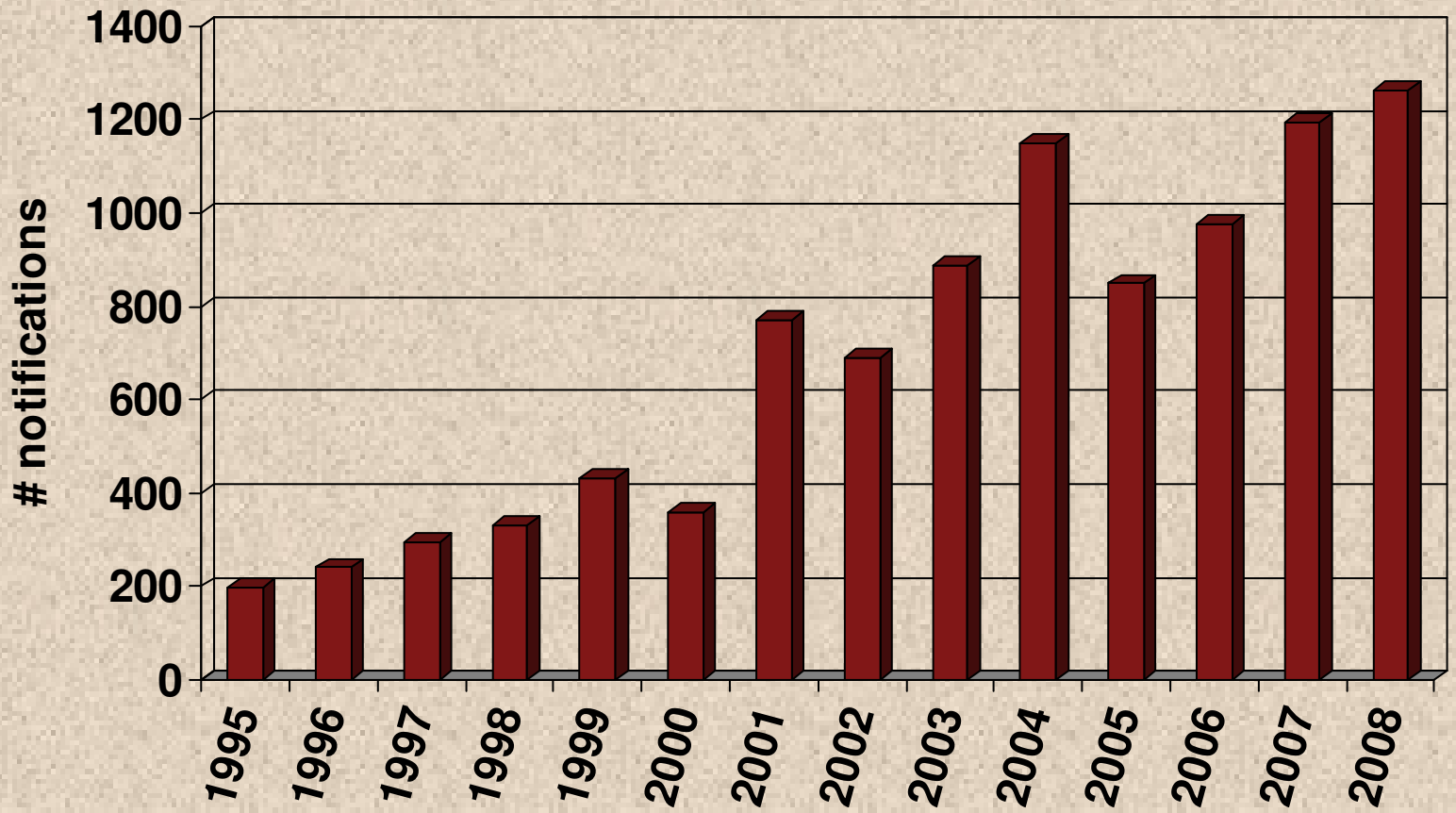
Human or animal health	*from*	**risks arising from additives, contaminants, toxins or disease organisms in food, drink, feedstuff**
Human life	*from*	**plant- or animal-carried diseases**
Animal or plant life	*from*	**pests, diseases, disease-causing organisms**
A country	*from*	**other damage caused by entry, establishment or spread of pests**

TRADE CONCERNS BY SUBJECT (1995-2008)



G/SPS/GEN/204/Rev.9 (Adds. 1-3)

SPS NOTIFICATIONS CIRCULATED



Source: WTO

TBT MEASURES TYPICALLY DEAL WITH

- Labeling of food, drink and drugs
- Quality requirements for fresh food
- Packaging requirements for fresh food
- Packaging and labeling for dangerous chemicals and toxic substances
- Regulations for electrical appliances
- Regulations for cordless phones, radio equipment etc.
- Textiles and garments labeling
- Testing vehicles and accessories
- Regulations for ships and ship equipment
- Safety regulations for toys
- Etc…..

SPS MEASURES TYPICALLY DEAL WITH

- Additives in food or drink
- Contaminants in food or drink
- Poisonous substances in food or drink
- Residues of veterinary drugs or pesticides in food or drink
- Certification: food safety, animal or plant health
- Processing methods with implications for food safety
- Labeling requirements directly related to food safety
- Plant / animal quarantine
- Declaring areas free from pests or disease
- Preventing disease or pests spreading to a country
- Etc……..

EXERCISE: CASE OF BOTTLED WATER

MEASURE - I

Materials that can be used because safe for human health

SPS

MEASURE - II

Requirement: no residues of disinfectant, so water not contaminated

SPS

MEASURE - III

Permitted size of bottle to ensure standard v

TBT

MEASURE - IV

Permitted shape to allow stacking and displaying

TBT

MEASURE - V

Government health warning:

"SMOKING IS INJURIOUS TO HEALTH"

Warning:

Objective – Human Health

Label appearance:

Typography, colour, size, position etc.

TBT

(Though the objective is health, its not for food)

Thank You

Intellectual Property Rights and Right to Health: A Human Rights Perspective

Anand Grover

UN Special Rapporteur on Right to Health

Director, Lawyers Collective

8 October 2009

The right to health under international law

The right to health is recognized in diverse International Instruments:

- Universal Declaration of Human Rights (Art. 24)
- International Convention on the Elimination of All Forms of Racial Discrimination (Art. 5(e)(iv) 1965
- Convention on the Elimination of All Forms of Discrimination against Women (CEDAW). (Art. 11(1)(f), 12, 14(2)(b)) 1979
- Convention on the Rights of the Child: Art (24) 1989
- International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families: arts. (28, 43 (e), 45(c).) 1990
- Convention on the Rights of Persons with Disabilities: art. 25 (2006)
- ICESCR Art. 12
- The Charter of Fundamental Rights of the European Union (2000)
- European Convention of the Protection of Human Rights and Fundamental Freedoms (1950)

International law: Domestic Law

In Monist systems on ratification, International Law is enforceable at law in local courts

In Dualist systems apart from accession, the country has to adopt domestic legislation to make the law enforceable

However, in a number of countries, International instruments once they are signed on to:

Allow the courts to interpret domestic law in harmony with the international instrument

Apply principles in the absence of contrary domestic legislation even if there is no domestic law

International Covenant on Economic, Social and Cultural Rights (ICESCR)

ICESCR Art. 12

Article 12.1 provides the definition of the right to health

- 1) "The States Parties to the present Covenant recognize the right of **everyone** to the enjoyment of the **highest attainable standard** of physical **and mental health**."
- 2) The **steps to be taken** by the States Parties to the present Covenant to achieve the **full realization** of this right shall include those necessary for:
  - the provision for the reduction of the **stillbirth rate** and of **infant mortality** and for the healthy development of the child;
  - the improvement of all aspects of **environmental and industrial hygiene;**
  - the **prevention, treatment** and **control of epidemic**, endemic, occupational and other diseases; **the creation of conditions** which would assure to all medical service and medical attention in the event of sickness."

Progressive realization: Available resources

- The right to the highest attainable standard of health is to progressively realized
- While the highest attainable standard of mental health does not have to be achieved immediately, at a minimum *State parties must show that **they are making every possible effor**t to promote and protect the right to health, especially mental health*
- They must show that they are maximum use of the **available resources TODAY** towards the progressive realization of the right to health
- This would also mean use of **International Cooperation**

Non-retrogression

- Coupled with progressive realization is the **principle of non-retrogression**
- There can be **no steps backwards**
- *Both impose the obligation to have **benchmarks** and indicators which allow for monitoring*
- However certain issues, e.g. Non-discrimination, non-consensual treatment: **No question of progressive realization**
- These are immediately applicable

The right to health framework

Non-discrimination : Universal Human Right Norm

- Definition: "*On the basis of Disability" means any distinction or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise on equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field. It includes of all forms of discrimination including denial or reasonable accommodation (CRPD: Article 2)*
- Human rights treaties were developed with a key to consider rights on a basis of non-discrimination.
- Non exhaustive grounds include: race, color, sex, language, religion, political or other opinion, national or social origin, property, disability, birth or other status
- States have an obligation to make health services available on a basis of non-discrimination and equality.

The right to health framework

General Comment 14 (2000), establishes a framework for the realization of the right to health.

Underlying conditions

- Safe drinking water and adequate sanitation
- Healthy nutrition
- Health related education and information
- Healthy working and environmental conditions
- Housing, Unemployment, Income support

And Determinants of health

- Addressing poverty
- Gender equality
- Non-discrimination and social inclusion

The right to health framework: Freedoms

- From **non-consensual** medical treatment (e.g. medical experiments and research or forced sterilization. This therefore includes- right to control one's health and body. With people living with mental health difficulties, health care providers must ensure to **respect the individual autonomy and dignity** of such persons.
- From **torture** and other **cruel, inhuman or degrading treatment or punishment**
- In Mental Health: **Involuntary treatment????**

The right to health framework

Elements of the right to health

Mental health services, goods, and facilities must be:

- **Available**: Health care facilities, health care providers available in **adequate numbers**
- **Accessible**: Physically and ge0graphically; economically (affordable); **non-discriminatory**; Information relating to be made available
- **Acceptable**: Respectful of culture and medical ethics
- Good quality

The right to health framework: Entitlements

- To Appropriate Health Care Services
- To Community based services
- To Availability of health care institutions
- To Access to essential medicines
- To Adequate health care providers
- To Provision of health-related education and information especially regarding health

The right to health framework: State Duties

- **Respect**: states must **refrain from interfering** directly or indirectly with the right to mental health
- **Protect**: States must **take measures to prevent third parties** from interfering with the right to mental health of its peoples.
- **Fulfill**: states required to **adopt appropriate legislative, judicial, administrative etc., measures** towards the realization of the right to mental health.

Fulfill Includes the following:

- **Facilitate**: states need to **take positive measures** that enable and assist individuals to enjoy the right to mental health.
- **Provide**: states need to provide a **specific right to individuals**, if they are unable for reasons beyond their control, to realize the rights themselves : **Specific support for person living with mental disability to take decisions**
- **Promote**: states need to undertake actions that create, maintain and restore the health of their people. E.g. Through **research and provision of information.**

Right to mental framework: entitlements

Participation: Community based model

The service users, the persons living with mental health difficulties, participate in health-related decision making at the national and community levels.

It has been demonstrated that:

- *community care has a better effect than institutional treatment on the outcome and quality of life of* people living with mental health difficulties
- *Shifting people from mental hospitals to care in the community is also cost-effective and respects human rights.*
- ***Mental health services be provided within the community, with the use of all available resources. Community-based services can lead to early intervention and limit the stigma of taking treatment.***
- ***Service users are participants (SUBJECTS AND NOT OBJECTS) in the whole process of service provision and decision making***

Right to Health framework

Proportionality

If any restrictions are to be imposed they must:

- Use the least restrictive approach
- Be proportional to the objective sought to be achieved

Monitoring and Accountability

- Integral to the success of realization of the right
- Duty bearers: States are held to account
- Independent body with sufficient powers to monitor and account
- This body must include persons living with mental difficulties

Rights Based (Evidence) Approach to Health

Rights Based Approach is different from the Right to Health framework

Rights Based Approach (RBA) appreciates that there is inequality in society; this inequality results in deprivation of rights of persons, including the right to health

RBA postulates that in order to realize the the Right to Health States have to promote the rights of persons deprived of those rights

Shown to work both anecdotally & epidemiologically

Anecdotally: Sonagachi sex workers project: **Empowering sex workers** on their civic and other rights empowered them to negotiate safe sex and negotiate condom use with their clients increased from 3% (1992) to 90% (1998) resulting in STD fell from 25% to 11%; HIV sero-prevalence rates raised from 5% to &%

This is now supported by **epidemiological data from South India**, in Tamil Nadu where sero-prevalence in women aged 15-24 yrs, tested nationally at ante-natal clinics shows a decrease of 54% between 2000-2007.*(Lancet Report, 26 July 2008)*

Community Empowered and Community Driven Approach key in HIV

WHAT IS A PATENT?

- Patent is an exclusionary monopolistic right
- It is given to inventors for a specific period.
- Why: To reward inventions and to induce R&D investment.
- In return the inventor discloses the invention to the public.
- Monopoly means => No Competition => results in monopolistic prices for patented drugs.
- Competition => helps in lowering the cost of drugs.

WHAT IS A PATENT?

- Types of patents: product and process.
- Negative right to exclude others from act of making, using, offering for sale, selling or importing for those purposes that product in India.
- Territoriality: Limited to jurisdiction of granting country
- Granted or refused according to laws of a particular country
- No international or cross-border patent

PATENT LAW AND IMPACT

- *Patents and Designs Act, 1911*:
  - Product and process patent protection
  - Term of patent: 16 years

- *Patents Act, 1970* (For pharmaceuticals and agrochemicals):
  - No product patent protection, only process patent
  - Process patent for best process known to inventor
  - Maximum term of patent: 7 years

- Consequence:
  - No monopoly on pharmaceutical products
  - Indian pharmaceutical companies used alternate, non-infringing processes to manufacture drugs
  - > 1 manufacturer of drug → competition → lower prices
  - Prices of medicines in India are the lowest in the world.
  - Indian companies supply generic drugs to other countries

INDIAN PHARMA GROWTH

Year	Bulk drug production (Rs million)	Formulation production (Rs million)
1947		100
1960		700
1970		2500
1974–1975	900	4000
1984–1985	3650	18,270
1990–1991	7300	38,400
1994–1995	15,180	79,350
1999–2000	37,770	158,600
2003–2004	77,790	276,920

Source: Sudip Chaudhari, *The WTO and India's Pharmaceutical Industry*

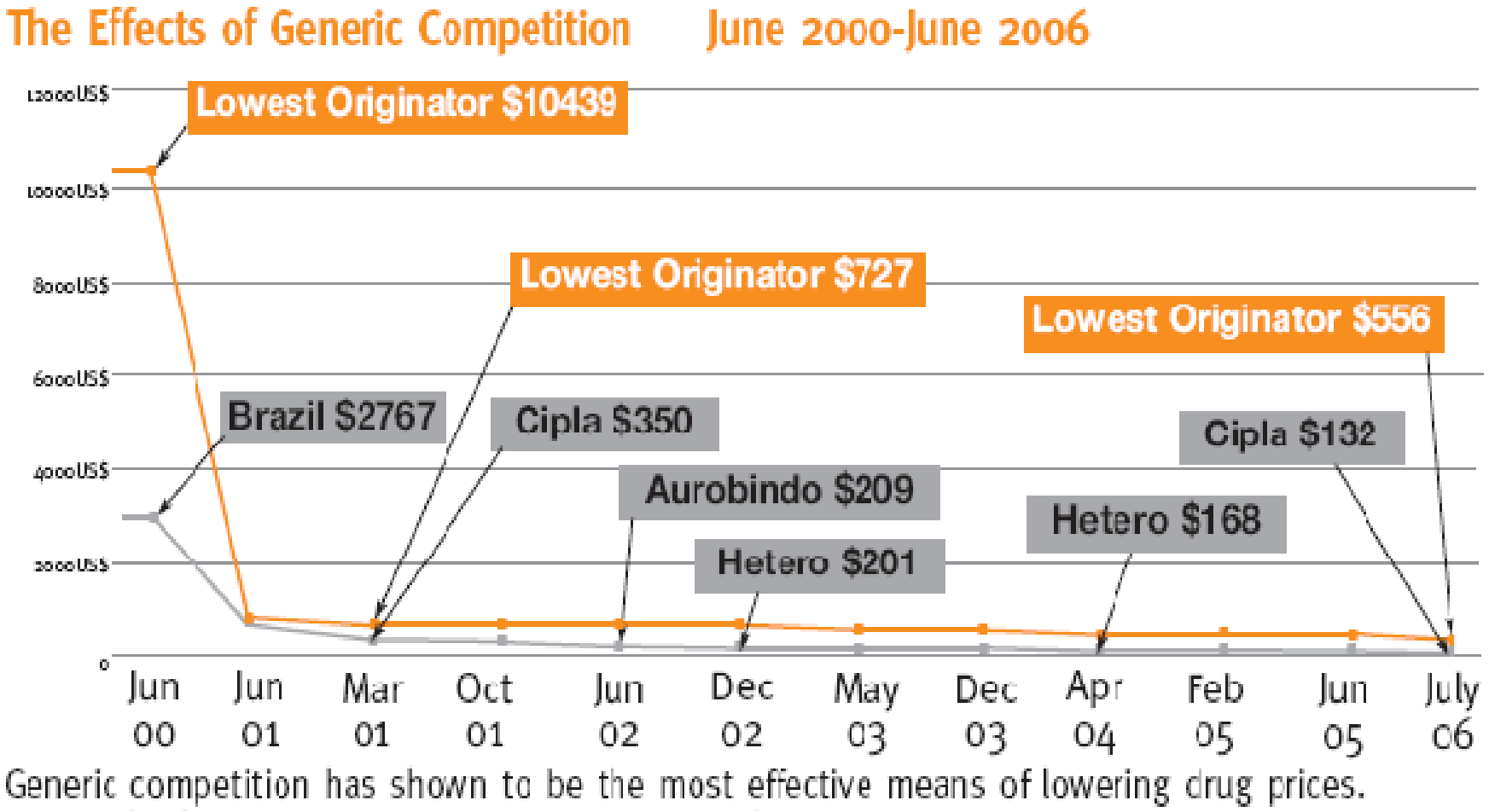
INDIAN PHARMA: EXPORT GROWTH

(USD million and %)

Year	Total exports	Total imports	Trade balance (col2/ 3)	Trade balance as % of exports
1973–74	47.9	43.8	4.1	8.5
1975–76	48.7	53.0	-4.3	-8.9
1979–80	87.9	148.2	-60.4	-68.7
1985–86	158.9	218.6	-59.7	-37.6
1988–89	322.9	308.6	14.3	4.4
1989–90	514.6	391.7	122.9	23.9
1995–96	698.7	558.1	140.5	20.1
1999–00	1668.5	346.6	1321.9	79.2
2003–04	3177.3	686.7	2490.6	78.4

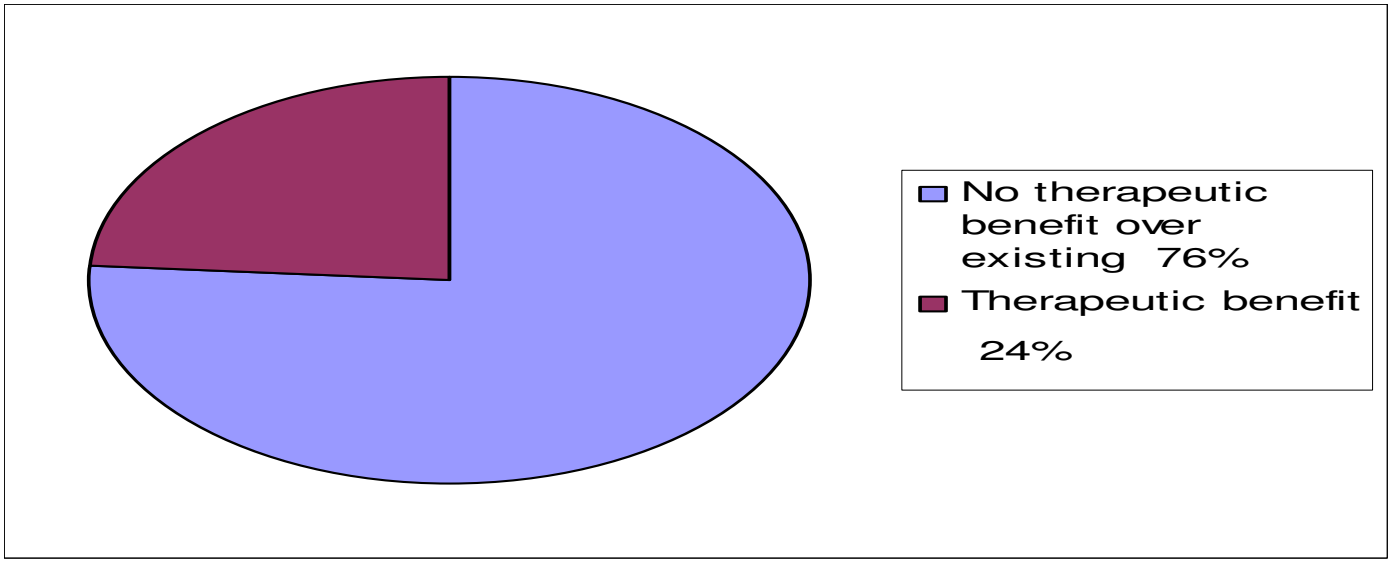
Source: Sudip Chaudhari, *The WTO and India's Pharmaceutical Industry*

Graph 1: *Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.*



Courtesy : Médecins Sans Frontières

NEW DRUG APPROVALS [1989-2000]



- 1,035 new drugs approved by US FDA (1989-2000)
- Only 15% of new drugs approved in 1989–2000 were highly innovative priority NMEs.
- India estimates 12,000 pharmaceutical applications have been filed mostly relating to incremental improvement over existing old drugs.

"Changing Patterns of Pharmaceutical Innovation", National Institute for Health Care, Management Research and Educational Foundation, May 2002

TRIPS REGIME

- Minimum standards of intellectual property protection with effect from 1 January 1995.
- What is patentable?: Invention which
  - is *new*,
  - involves an *inventive step* and
  - is *capable of industrial application*. [Article 27]
  - However, these terms have not been defined in TRIPS. These are the are flexibilities for member states.
- Protection to both products and processes [Article 27]
- Period of protection: Minimum 20 years [Article 33]
- TRIPS is not a stand-alone agreement and has to be seen within the broad framework of international law.

TRIPS AND DOHA DECLARATION

- Does not override existing international obligations under ICESCR and ICCPR, which include
  - Right to life, right to food, right to health
  - Right to enjoy the progress of science and technology

- *Doha Declaration on TRIPS Agreement and Public Health, 2001*:
  - Reaffirms the right of WTO Members to use the flexibilities under TRIPS
  - TRIPS to be interpreted as per objectives (Article 7) and principles (Article 8)
  - TRIPS does not and should not prevent countries from taking measures to protect public health.

EVERGREENING

- Pharmaceutical companies obtain patents on different aspects of the same drug to extend their monopoly e.g: formulations, salts, esters, dosages, combinations, crystalline forms, pro-drugs despite the fact that the therapeutic substance is the same etc.
  - Combivir: Combination of Zidovudine and Lamivudine
  - Imatinib base to Beta crystalline form of Imatinib mesylate
  - Interferon and pegylated form of interferon
- Due to this, a single drug has multiple patents → patent thickets
- This prevents introduction of generic versions of the drug even after the expiry of the original patent.
- RESULT: Denial of access to cheaper generic versions

INDIAN PATENT LAW AMENDMENTS

- 26 December 2004: Ordinance was promulgated to extend product patent to pharmaceuticals.

- March 2005:
  - Parliament deliberated the issue of pharmaceutical patents and acknowledged problem of evergreening.
  - Patents (Amendment) Act, 2005 passed.

- Introduced 20-year product patents for pharmaceutical products.

- TRIPS flexibility was used and included key protections:
  - Section 3(d) amended to exclude patentability of new forms of known substances unless there is significant enhancement of efficacy;
  - Pre-grant opposition retained;
  - Post-grant opposition introduced.

OBJECTIVE OF SECTION 3(d)

- To prevent evergreening: What are not inventions [Section 3(d)]
  - 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 of a known substance …

    Explanation: "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

IMPACT OF PATENTS ON ACCESS – *GLEEVEC* CASE

- 2003: Novartis granted exclusive marketing rights for *Gleevec*, an anti-cancer drug.
- January 2006: Indian Patent Office rejects Novartis' patent application on the basis of section 3(d), lack of novelty, inventive step and convention country application.
- June 2006: Novartis challenges section 3(d) as violating TRIPS Agreement and Constitution of India. **Efficacy is vague**.
- August 2007: Madras High Court upholds section 3(d).
- '**Efficacy' not vague,** but **therapeutic efficacy**
- **Enacted *to provide easy access to life saving drugs and to meet the constitutional obligation of the State to provide good health care to its citizens.***
- June 2009: IPAB held Novartis was not entitled to a patent on imatinib mesylate on the ground that section 3(d) – significant difference in therapeutic efficacy – standard not satisfied
- August 2009: Novartis filed SLP in Supreme Court challenging the patent rejection by IPAB.
- Novartis wants a reinterpretation of section 3(d): **Efficacy: Any improvement**.

SECTION 3(d) - CHALLENGES

According to US India Business Coalition

- 65% of the new drug approvals in the US is for incremental innovations
- Leading Indian Pharma Companies are investing approx. 12-18% of gross revenue in R&D
- Knowledge Commission: 76.4% of inventions of Indian companies are incremental innovations (37.3% are breakthrough: not new NCEs)
- To invent & develop a new drug costs over USD 1 billion
- Incremental innovations are an incentive for the pharma industry.
- Section 3(d) is the hurdle for patenting of incremental innovations in India.
- Therefore, section 3(d) should be deleted from the Patents Act

SECTION 3(d) – CHALLENGES

Mashelkar Committee

- Technical Expert Group [TEG] headed by Mashelkar set up by Government after assurance to Parliament:
- Terms of reference of TEG :
  - Whether patenting with respect to pharmaceutical substances should be limited to NCEs
  - Whether micro-organisms can be excluded
- Revised report states that limiting patenting to NCEs might violate TRIPS (on what basis? no reasoning is afforded)
- Incremental innovations are a norm in the pharma industry should be permitted (this was not its mandate)
- Comment on section 3(d) though not mandated??
- What US India Business Coalition says openly, Mashelkar committee says indirectly.

SECTION 3(d) –IMPLEMENTATION

- Patent offices are not implementing 3(d) according to the Madras High Court or the IPAB judgment in the Novartis case.
- IPA study: Study of 67 patents granted prima facie did not satisfy the test under 3 (d) and/or 3 (e)
- Study by IPR law depatrment, NUJS, Kolkata [based on information from patent office website]:
  - 9,719 patent applications for drugs 2005 to 2008; 2734 granted;
  - 58 opposed: 34 Oppositions (Pre-grant and Post grant); 24 others
  - Of 58, 41 patent applications were rejected; 27 under section 3(d)
- Pharmaceutical patent applications: about 12,000 (2007, LCHAU).

FREE TRADE AGREEMENTS (FTAs)

- FTAs are bilateral and regional trade agreements generally between two countries.
- Due to the reluctance of the multilateral system in the WTO to introduce new changes providing higher levels of IP protection, the US has chosen to rely on the bilateral approach.
- These agreements:
  - Restrict TRIPS flexibilities and/or
  - Introduce TRIPS-plus provisions
- These measures are termed as TRIPS- plus provisions- as these are not covered by the TRIPs agreement.
- These bilateral agreements require higher IP standards.
- Lack of transparency in FTA Negotiation.

DATA EXCLUSIVITY (DE)

- Article 39 of TRIPS requires protection of data submitted to regulatory authorities for approval of pharmaceuticals and agrochemicals.
- Multinational pharmaceutical companies have been lobbying with the Government for DE which will restrain the drug regulatory authority from relying on test data submitted by pharmaceutical companies to approve generic versions of the same drug.
- DE will allow monopolies to be created even in case of non-patentable or off-patent drugs.
- It may also extend the monopoly beyond patent term in some cases.
- Satwant Reddy Committee Report (2007): With respect to pharmaceuticals,
  - Provide minimum standards of data protection during a transitory period.
  - In the post-transition period, higher standards of data protection can be considered for “new chemical entities”.

WHAT IS PATENT LINKAGE?

- **Patent Linkage** links the patent system to the drug regulatory authority system.

- **How it works**
  - Drug Controller asks those applying for marketing approval for patent status of drugs.
  - If applicant reveals that the drug is patented, then the Drug Controller will not proceed with application (unless patentee consents)

- **Effect**
  - It delays marketing approval of generic drugs in the market until after patent expires.

- **Objective**
  - To prevent the registration and authorisation of generic versions of a patented drug for marketing until the expiry of the patent.

- **No such system exists in India**.

- Not required in TRIPS. This is a TRIPS-plus provision.

- Requirement of patent linkage is a standard clause in many bilateral FTAs negotiated by US.
  - US FTAs with Singapore, Chile, Morocco, Bahrain

EXTENSION OF THE PATENT TERM

- TRIPS provides for a 20-year patent protection term
- FTAs require: Increase the term of Patent for more than 20 years
- Significant impact on access to medicines
- Pose burden on national health budget
- For instance, United States-South Korea FTA
  - A four-year extension would cost US$ 722.5 billion on the national health insurance for South Korea.

ENFORCEMENT OF IPRs

- TRIPS Plus provisions :
  - Civil remedies:
    - Compulsory damages
    - Expands injunction to intermediaries whose services are used to infringe IPR (eg bulk drug supplier),
    - Imposes obligation on intermediaries to disclose information
  - Criminal sanctions for infringement of all IP rights, including patents.
    - Applies not only to import, but to export, re-export, goods in transit
    - Action by State is mandatory
  - Border Measures
    - Includes patents
    - Applies not only to import, but to export, re-export, goods in transit
    - Action by State is mandatory
- Criminal sanctions include:
  - Imprisonment, monetary fines, confiscation of equipment and products, destruction of goods to permanent closure of involved establishments.
  - Grant of patents are never conclusive and have been challenged and found invalid.

Competition Law / Policy

An Introduction to various aspects

8 October 2009, New Delhi

Forms of Competition & market

- Perfect competition
- Monopoly
- Monopolistic competition
- Oligopolistic competition

*Pharmaceuticals an imperfect market

Hurdles to competition

1. Collusive agreements (cartels)
2. M&As
3. Abuse of dominance
4. Unfair trade practices (UTPs)

Collusive agreements

- Horizontal agreements (hard core cartels)
  - Price fixation
  - Market allocation
  - Output restriction
  - Bid rigging
- Vertical agreements
  - Refusal to deal
  - Tie-in arrangements
  - Exclusive dealing
  - Resale price maintenance
  - Territorial allocation

M&As

- M&As
  - Horizontal
  - Vertical
  - conglomerates
- Horizontal – could have competition concerns
  - If results in monopoly, or
  - If the outcome is a dominant player

Abuse of dominance

- Abuse, not dominance *per se*, a competition concern
- Possible abuses:
  - Excessive pricing
  - Refusal to deal
  - Tie in sales
  - Exclusive dealing
  - Exclusive territories
  - Predatory pricing
  - Raising rivals cost

Unfair Trade Practices

- False or misleading information etc.
- Generally dealt in consumer protection law
- Few competition regimes deal with this

Indian competition regime

- MRTP Act – becoming extant - New Competition Act, 2002
- FM, Budget speech, Feb99: “The MRTP Act has become obsolete in certain areas in the light of international economic developments relating to competition laws. We need to shift our focus from curbing monopolies to promoting competition…”
- Oct’99, Government constituted a High Level Committee on Competition Policy & Law under chairmanship of SVS Raghavan

Indian competition regime…

- May, 2000, Raghavan Committee submitted its report to Government
- It recommended enacting new competition act, set up CCI, repeal MRTP Act and wind up MRTP Commission
- Subsequently a Drafting Group under Dr. S. Chakravarthy was set up to draft a Bill taking into account the Raghvan Committee report
- The Competition Bill of India, 2001 was introduced in the Parliament and was referred to Parliamentary Standing Committee
- The Competition Act, 2002

Competition Act, 2002 highlights

- Hard core cartels prohibited *per se*
- Regulation of M&As have threshold; noticification optional
- Abuse of dominance and not dominance *pre se* frowned upon
- Higher penalties; however no criminal penalties
- UTPs dropped; passed on to CPA
- Emphasis on competition advocacy
- Constitution of competition fund

International competition regime

- Reasonable interface b/w trade & competition
  - Market access for imports
  - Market power in export market
  - Foreign investment
  - Intellectual property rights

International competition regime…

- No one regime, but efforts were made
- Havana Charter – after WW II
  - Tended to establish ITO
  - Art. 46: “each member shall take appropriate measures and shall cooperate with the Organisation to prevent, …, business practices affecting international trade which restrain competition, limit access to markets, or foster monopolistic control…”
  - ITO never came into existence

International competition regime…

- In 1958, Contracting Parties of GATT - Group of experts - to recommend – whether and to what extent they should undertake to address the issue of RBPs in international trade.
- In 1960, CP of GATT, based on EG's report, adopted Decision on Arrangements for Consultation on RBPs: at the request of any CP, a CP should enter into consultations on harmful RBPs in international trade on bilateral or multilateral basis. (invoked only thrice in 1996)

International competition regime…

- The competition issues were also raised during Uruguay Round – no consensus
- Competition related provisions in WTO acquis:
  - GATS articles 8 and 9
  - TRIPS: Articles 8, 40 and 31
  - TRIMS: Article 9
  - Others: Agreement on Safeguards, TBT, SPS, GP

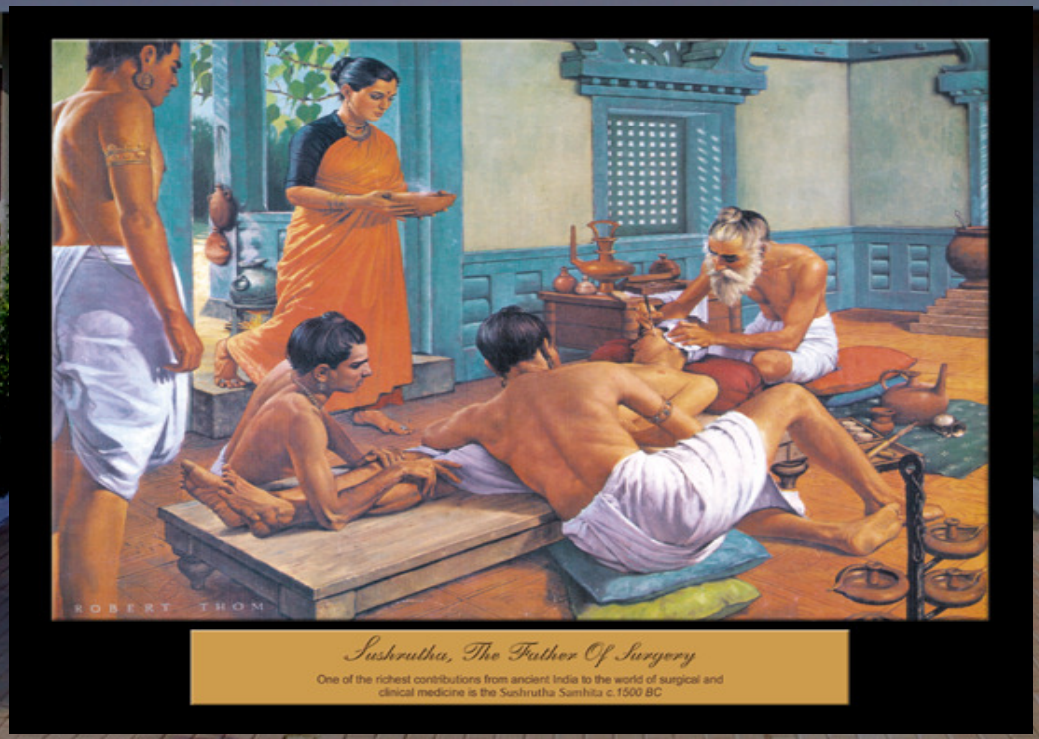
International competition regime…

- Working Group on Trade & Competition (WTO)
- 1996 Singapore WTO Ministerial Decln, para20:
  - Establish a WG to study issues raised by Members relating to interaction b/w trade & competition policy, including anti-competitive practices, in order to identify any areas that may merit further consideration in the WTO framework.
- …to ensure that development dimension is taken fully into account…
- Nothing concrete has come out from WG, participation was less (EU and Japan are/were most enthusiastic; US does not really backed it up)

International competition regime…

- Doha, 2001, recognized the case for a multilateral framework to enhance the contribution of competition policy to international trade and development…
- In July 2004, GC of WTO decided that trade and competition policy would no longer form part of the Doha Round

Contemporary relevance of India's Medical Heritage



Two Streams

•*The Indian medical heritage flows in two streams, one folk (Prakrit) and other scholarly (Samskrit) which is codified.*

• *Revitalisation of India's medical heritage calls for putting new life into both streams and not only support for the codified knowledge systems.*

Relationship between folk and codified streams

There are two key Sanskrit words that describe the relationship.

These are pra-krit & sams-krit.

The word prakrit refers to empirical knowledge that is ecosystem & ethnic community rooted.

It is not learnt from books. It is received through observation from p*rakriti* or nature.

The range of ***the prakrit knowledge traditions*** includes not only health practices but also vernacular languages, arts, music, weaving, agriculture and architecture.

The prakrit knowledge holders are self-taught, the teacher is nature. Prakrit knowledge is practical and functional. It does not depend on higher knowledge of principles and laws of nature.

Relationship between folk and codified streams

Sams-krit refers to such phenomenon (krit) that has been refined or modified, (samskar – from the prakrit state) and developed through abstraction, theorization & generalization into a sophisticated knowledge system.

It refers in Indian tradition to the various codified bodies of knowledge or shastras like linguistics and grammar (vyakaran), the fine and performing arts (shilpa, sangeet, natya, nritya etc.,), agriculture (krishishastra), architecture (vastu shastra) and healthcare (ayurveda).

This knowledge is sophisticated because it distills principles (tatvas) rules or laws (shastra) and their applications (vyvhar).

Relationship between folk and codified streams

In Indian society the samskrit traditions have always enjoyed a symbiotic relationship with the prakrit just as samskriti is derived from prakriti.

Thus the folk health traditions and Ayurveda are interconnected. The former are rich in practice and the latter have both sophisticated theory as well as practice.

One should not therefore plan for the revitalization of India's medical heritage without envisaging the development of both its prakrit (folk) and Samskrit (scholarly) traditions.

Example of Tulsi

Folk Knowledge	Codified Knowledge
Tribals use it for curing itching due to insect bite	Reduces anabolic and neurological activity, increases inflammation

Profile of folk medicine

There are estimated to be one million specialized carriers of folk medicine.

Their number is larger than all the para-medics on the pay –rolls of the government.

They have no legal status but enjoy a definite social legitimacy in their own localities.

These specialized carriers are birth attendants (6,00,000) bone-setters (60,000) herbal healers (1,00,000) healers who treat *"visha"* (60,000) i.e. poisonous snake, scorpion bites and rabies; and vets (60,000).

These carriers are seen across the length and breadth of the country, from Ladakh in the trans-himalayas down to Kanyakumari and across central India up to the North East.

Oral transmission-Incredible pedagogy

The transmission of folk knowledge illustrates a remarkable learning system.

There are no institutions promoting or co-coordinating the transmission of knowledge.

Yet a million specialized carriers and several millions of households geographically spread out across the country learn about properties of medicinal plants, bone-setting, midwifery, management of poisonous snake bites and such complex subjects.

Profile of codified medical knowledge

The codified stream consists of medical knowledge systems like Ayurveda, Siddha, Tibetan & Unani.

There are currently 6,00,000 licensed practitioners of the codified system who are recognized and registered by the state governments under the Indian Medicine practitioners Act.

The codification of the ayurvedic knowledge system has been going on from 1500 BC to 1900 AD.

It is documented in an estimated 100,000 medical manuscripts covering eight fields of medicine viz; *Kaaya chikitsa* (general medicine), *Bala chikitsa* (paediatrics), *Gruha chikitsa* (psychiatry), *Oordhwanga chikitsa* (ENT & Eye), *Salya chikitsa* (surgery), *Damshtra chikitsa* (toxicology), *Jara chikitsa* (rejuvenation) and *Vajeekarana chikitsa* (virilification).
[

Natural resource base of Indian Medical Heritage

Both the folk and codified streams extensively use natural resources.

Together they know of the medical uses of over 6000 species of native plants, around 400 species of animals and about 70 minerals and metals.

Natural resource base of Indian Medical Heritage

Examples of Medicinal Plants

Zingiber officinale

Phyllanthus emblica

Bacopa monnieri

Adhatoda zeylanica

Tinospora cordifolia

Punica granatum

Azadirachta indica

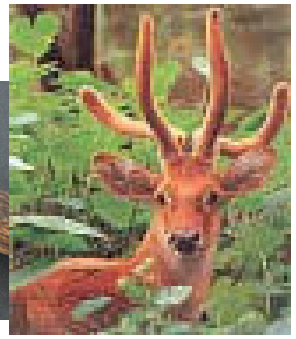
Moringa oleifera

Natural resource base of Indian Medical Heritage

Examples of Medicinal Animals

Lac

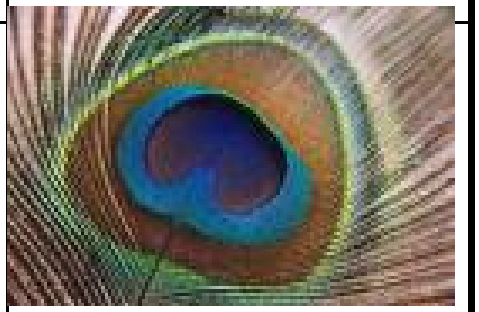
Deer horn



Cows urine

Earth worm

Leeches



Peacock feather

Natural resource base of Indian Medical Heritage

FRLHT

Examples of Medicinal Metals and Minerals

Sulfur

Mercury

Iron

Gold

Cinnabar

Theoretical foundations

The codified stream has sophisticated theoretical foundations.

It has dynamic and systemic theories of physiology; pathogenesis; pharmacology and pharmaceuticals.

Different from the structural theories of western bio-medicine.

The Epistemology of Ayurveda

In order to appreciate and realize the contemporary relevance of India's medical heritage, it is extremely important to take note of the fact that the *ways of knowing* (epistemology) about nature in traditional Indian health Sciences.

Due to a euro-centric appraisal of Ayurveda a simplistic conclusion is that because the Ayurvedic knowledge system does not fully correspond, with the methods and categories of Science, it must therefore be inherently deficient.

The comparative Epistemology of Ayurveda and Science

The differences between Ayurveda and western biomedical science arise due to their fundamentally different epistemologies.

They both use the same six human instruments of knowing that all human beings are endowed with namely the five senses and the mental faculty, but they use them differently.

The depth, range and scope of knowledge they therefore discover are different. Science has an incredibly detailed knowledge about *parts* of physical and biological Nature, like sub-atomic particles, atoms, molecules, cells, tissues, organs

The Traditional Knowledge Systems have an amazingly holistic knowledge of the physical, biological and spiritual *fields* in Nature (atman, dik, kal, manas, akash, vayu, agni, jal, prithvi).

The Epistemology of Science

Science studies Nature from the standpoint of an observer (Scientist) separated from the observed (Nature).

The five senses are employed, alongside an ever-increasing range of extremely sophisticated scientific tools that dramatically extend the range and depth of the senses, to gather sensory data about Nature.

Nature thus discovered by Science is limited to that aspect that is available to the *senses*. It is a hugely diverse physical and biological world that appears in terrestrial, subterranean, aquatic and extra-terrestrial space.

This sensory data about the physical and biological world is then analyzed with the aid of the intellectual faculties of the mind, using tools like Logic and Mathematics and coherent conclusions are arrived at.

The Epistemology of Science

In this observer-observed frame one is bound to obtain partial views of Nature

From the standpoint of an observer separated from the observed, the scientist can never view the whole.

A part can only view another part. The parts of physical and biological Nature thus discovered while being detailed in terms of their structure, functions and their dynamics of change nevertheless provide an incomplete understanding of the whole.

Epistemologically, Western Science is thus characterized as being reductionist.

Holistic framework of Ayurveda

The Traditional Knowledge Systems do not only adopt the observer-observed frame for the study of Nature.

The scientists immerse themselves into Nature and study it *by becoming one with* it.

Oneness cannot be achieved by the senses because they are naturally compartmentalized. The eyes can not hear and the ears can not see. Each sense organ is restricted by Nature to its particular domain.

Oneness is therefore achieved with the aid of an advanced application of the mental faculty. In this application the mind of a *trained* seeker of knowledge (rishi) is *rendered still and silent.*

The application requires rigorous training (sadhana). It is the still, silent, state of mind, empty and free of thought, that is referred to as the *oneness* state because in this state it naturally experiences oneness and acquires the natural insight to see *fields* or whole phenomena

Outline of Ayurvedic Biology a field theory

Five states/fields of matter	Tastes of materials dominant in particular states of matter	Dominant Sensory attributes of the five states	Key Bio-physical and bio chemical Properties of different states	Biological Actions of five states
Parthiva/ solid state	Sweet Astringent	Smell (Nose)	**Guru,** Heavy; Difficult to digest, difficult to disintegrate in cellular metabolism	Tissue building, growth, Weight, Compactness, Stability, Strength,
Apya / Liquid state	Sweet Astringent, Sour Salty	Taste (Tongue)	**Sita,** Slow thermodynamic changes, promotes cellular integrity, conjugation and binding, increases life span of cells and supports anabolic activities in general	Improving tissue quality. Moistening, Oleation, binding.
Tejasa/ heat/ plasma stage	Pungent Sour Salty	Vision (Eyes)	**Usna,** Releases and conducts heat, increases cellular metabolic rates and improves fluid movements, causes perspiration and decreases life span of cell life. Supports catabolic activities in general.	Metabolism, Lustre, Complexion,
Vayavya /Gaseous stage	Astringent Bitter	Touch (Skin)	**Laghu,** Light; Easy to get disintegrated and absorbed in various metabolic stages	Neurological functions
Akasiya / ether, space	Unmanifest	Sound (Ear)	**Sooksma:** Subtle, Spreads rapidly at micro level in intercellular space, and augments neuro	Neurological functions

Recent contributions of India's medical heritage

During the last century both the folk and codified streams like Ayurveda have been making small but strategic contributions to healthcare.

These contributions signal the potential of India's medical heritage

Recent contributions of India's medical heritage

In a recent Science Initiative on Ayurveda, the Government's Department of Science and Technology has supported *basic* research focused on subjects such as

The genomic basis of Ayurvedic phenotypes,

Metabolic and immunologic correlates of the traditional procedure of detoxification (pancakarma),

Microstructure of metal-based Ayurvedic drugs in powder form.

Recent contributions of India's medical heritage

The folk stream has also demonstrated its potential.

Recent studies establish beyond doubt that the folk practice of storing drinking water in copper vessels is probably the world's cheapest solutions for microbial purification of water.

Within 16 hours of contact with copper *Escherichia coli*, *Salmonella, cholerae* bacteria are completely destroyed.

Recent contributions of India's medical heritage

Studies by a Nobel laureate have established that the dried powder of the whole plant *Phyllanthus Amaras* used largely in the folk tradition for hepatic disorders, is effective against viral hepatitis.

Pre-clinical studies show that the aqueous extract of the tree *Holarrhena pubescens* commonly used by folk communities for treatment of diarrhea prevents colonization of the gut

Critical policy gaps

Since India's first five year plan (1947-1952) right up till the current ongoing 11th five year plan (2007-2012), the Indian Systems of Medicine (ISM) have received around 3% of the national health budget.

With this scale of investment the fuller potential of Ayurveda and other Indian system of medicine (ISM) may not be realized.

The challenge in this regard is to raise the scale of government investments on the traditional systems of healthcare to around 20-25% of the national health budget.

Why traditional medicine has been neglected

Despite the spectrum, depth and widespread practice of Indian systems of medicine there are still scientists in India and other countries who believe that traditional medical knowledge is irrelevant for contemporary needs.

This *clouded* view probably has its origin in colonial and post colonial history when deliberate attempts were made to distort the value of non-European indigenous knowledge systems as part of a political strategy of domination.

The skewed story of small pox

In the context of healthcare it is worth recollecting the implementation of the colonial strategy in the story of small pox.

Incomplete versions of the contemporary history of western medicine in India inform us that one of the biggest contributions of western biomedicine is the eradication of small pox through the application of the Jenner vaccine.

The skewed story of small pox

However this history fails to inform what was reported in the account of the British physician Dr. J. Z. Holwell, FRS,.

Around 1758 this is what Dr. Holwell concluded about the indigenous small-pox procedure in his report to the college of physicians in London.

‘*when the before recited treatment of the inoculated is strictly followed, it is next to a miracle to hear, that one in a million fails of receiving the infection, or of one that miscarries under it*.

The skewed story of small pox

Inoculation against the smallpox was widely practiced, in India, till around 1790.

It was subsequently maligned and banned by the colonial administrators from around 1802.

This story of small pox suggests that modern Indians have been fed with a one sided version of the modern history of the medicine which appears to have exaggerated the achievements of western medicine in respect of its contribution to the eradication of small-pox.

FRLHT Confusion regarding the relationship between the traditional and modern

In colonial times the indigenous intelligentsia of not only India but dozens of colonized countries were misled into believing that modernity was no longer to be a natural evolution from their own past into their present

It had to be imported from the advanced west.

This belief even persists today in many minds which have not awoken from the colonial stupor.

Confusion regarding the relationship between the traditional and modern

Just as the past and present lie on a continuum and the present evolves from the past so does the modern evolve from the traditional

Modernity could in fact be aptly described as “evolving tradition”.

Confusion regarding the relationship between the traditional and modern

In this perspective of modernity, there can be no uniform model of modernity.

It must evolve as a multi-cultural process with a diversity of models, world-views, life-styles products and services.

It is such cultural diversity that can spur civilizational evolution which today has been somewhat arrested due to a mono-cultural superimposition.

The promise of new models of modernization

Scientists & planners concerned with modernization need to understand that while all societies can share, adapt & even borrow and learn from each other, the core of their modernity must derive from their own roots.

Therefore the building of knowledge societies in the 21st century should *not* be viewed as a mono-cultural process but rather as a multi-cultural program wherein many different flowers bloom.

The Tran-disciplinary challenge

Is there a Framework for Integrating Ayurveda and bio-medical Sciences?

This question is equivalent to asking the question can the whole and its parts be related?

Or the question, are *fields* and the several structures contained therein related?

The Tran-disciplinary challenge

It is obvious that the whole and part are related

The key point to be understood is that the relationship is not one to one because the whole is not equal to the part and nor do the sum of parts add up to remake the whole.

One should therefore not be seeking *equivalence* in developing this relationship otherwise one will either reduce the whole to a part or assume the part represents the whole and thus develop a distorted understanding.

The promise of bridging Ayurveda and Bio-medicine

The collaboration between bio-medicine and Ayurveda can be very fruitful.

There are incredible details of parts that biomedical sciences uncover that can enrich the understanding of the whole

Similarly there are new perceptions, insights and non-sensory dimensions that are revealed in a holistic view that can fundamentally alter the partial outlook.

The future of healthcare

What is the key challenge facing India's medical heritage in the 21st Century?

Recent health seeking behavior studies clearly suggest that consumers all over the world realize that no single system of healthcare has all the answers to their health needs.

Western bio-medicine excels in surgery, and in the management of acute conditions

Traditional systems like Ayurveda appear to have balanced solutions to the management of common ailments, chronic metabolic disorders and for prevention and well being.

Integrative medicine: a new model for 21st century

A new model of integrative health-care delivery which includes *Complementary and Alternative Medicine* (CAM) is thus emerging on the world stage.

It appears that in future medical education, research and health services will need to prepare themselves for a regime of *integrative medicine* as the strategy for universalisation of health care.

School on Trade and Public Health

Data Exclusivity: An Economics Perspective

Madhukar Sinha

Wednesday, October 07, 2009

Programme

Pricing in the absence of competition

Pricing strategies for products

Data security vs. Data exclusivity

Recommendations of the Satwant Reddy Committee

Price and Costs

Price = Cost + Margin

Costs

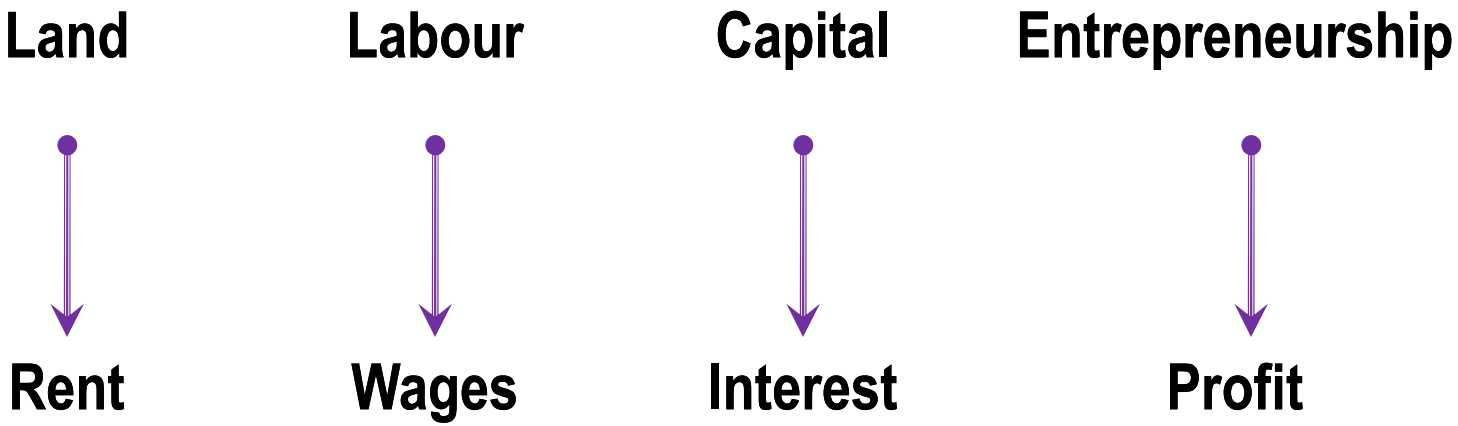
$$C = c_1 + c_2 + \ldots + c_n$$

$$\sum_{i=1}^{n} C = c_i$$

Price and Costs

Price = Cost + Margin

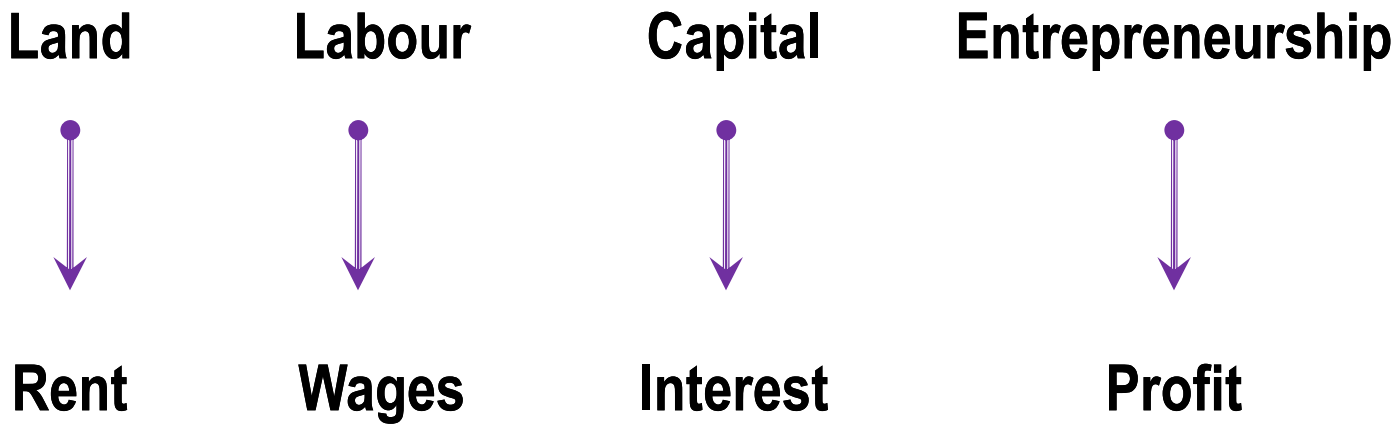
Factors of production



Price and Costs

Price = Cost + Margin

- Competition => Just payments => Margin → 0



Price and Costs

Price = Cost + Margin

What about intellectual property?

Land	X
Labour	X
Capital	X/√
Entrepreneurship	X/√
Knowledge	√

Knowledge as a new factor of production?

Price and Costs

Price = Cost + Margin

Disclosures in the Profit and Loss A/c of the firm

Rent	√
Wages	√
Interest	√
Profit	√
Intangibles	?

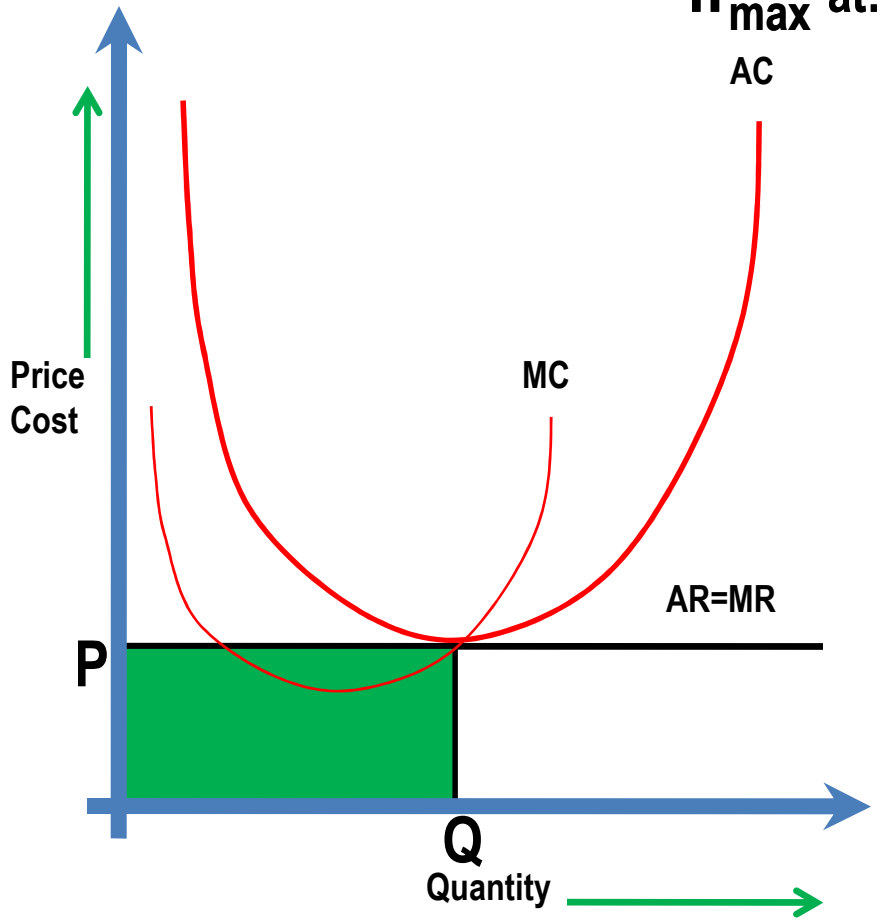
Hence, Price = Cost ~~+ Margin~~

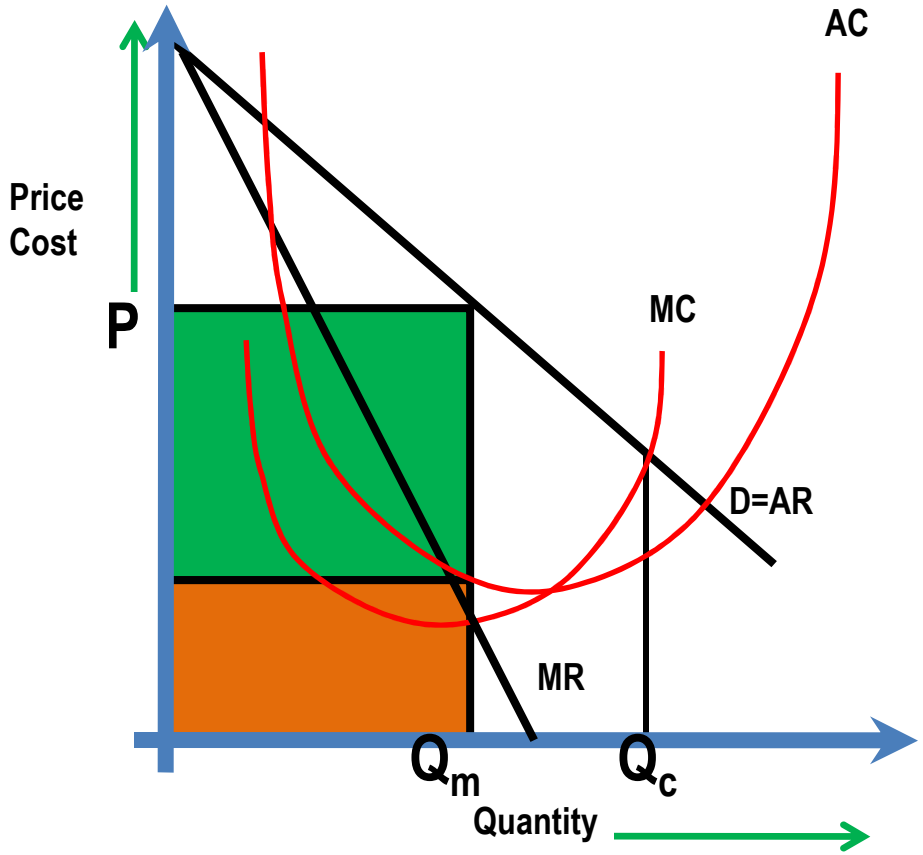
Price and Costs

Revenue= Price x Quantity

π= Total Revenue – Total Cost

π_{max} at: MR = MC and P = AR





Price and Costs

Price = Cost + Margin

Barriers to entry=>Single Seller=>Margin>0

Large Single Seller=> Large Buyer in market for factors of production

Large Buyer=> Prices paid would be negotiated downwards

Single Seller=> Margin>>0

Incentives to restrict access to market by competitors very high

Pricing Strategies

Bases

Costs – Fixed and Variable

Competition

Company objectives

Positioning Strategies

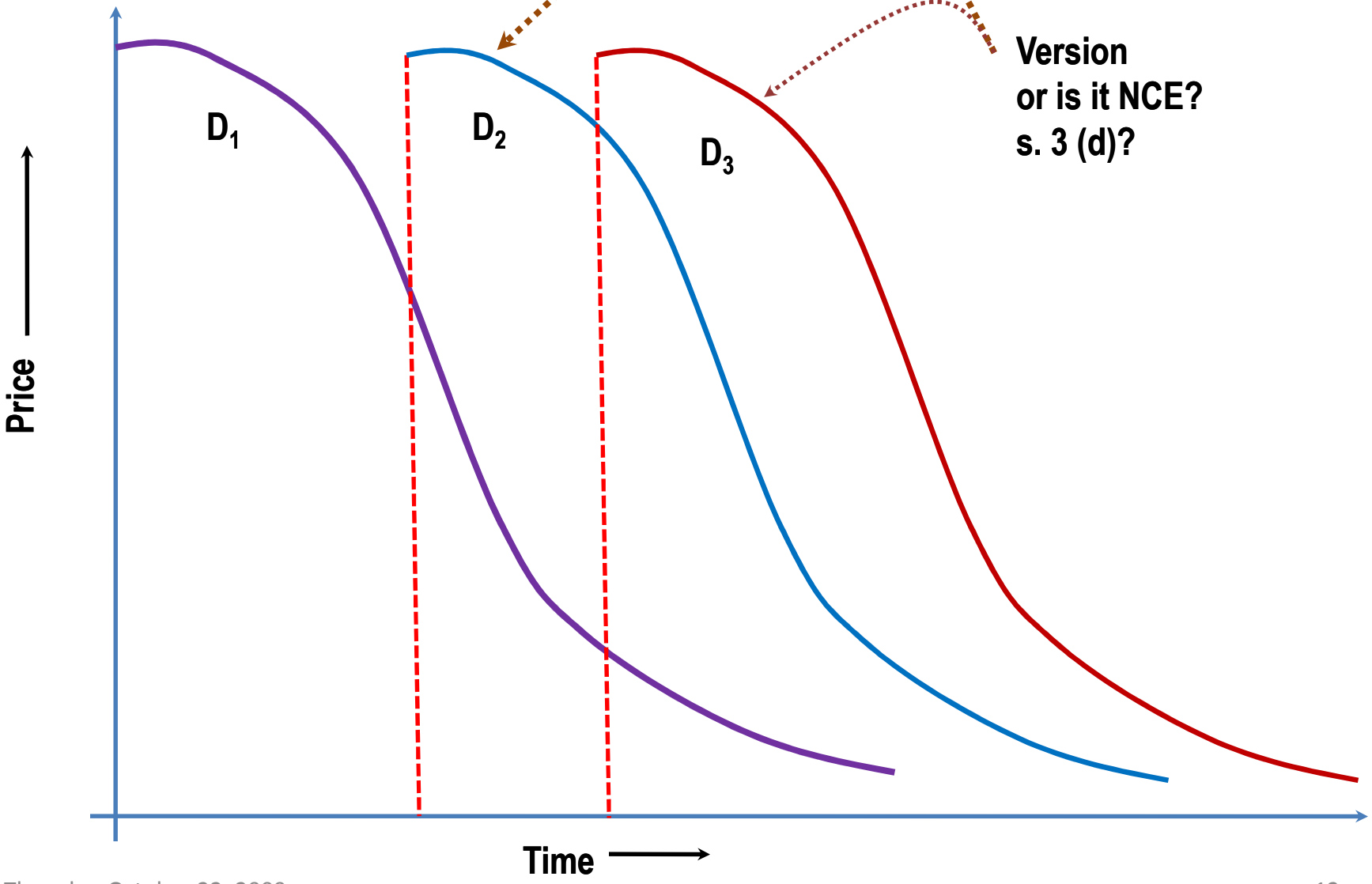
Target Group and Willingness to pay

Ability to pay?

Pricing Strategies

Bundle	Premium
Cost-plus	Product line
Discrimination	Product – Optional
Economy	Product – Captive
Geographical	Promotional
Limit	Psychological
Loss Leader	**Skimming**
Penetration	Value
Predatory	Versioning

Pricing Strategies



Data Security

Keep data from corruption

An issue of privacy

Trade Secret?

Data Exclusivity

Data is revealed for Statutory purposes

Regulatory Authority is privy to the data

Demand: Do Not Reveal Data

Since data is the basis for working of the patent

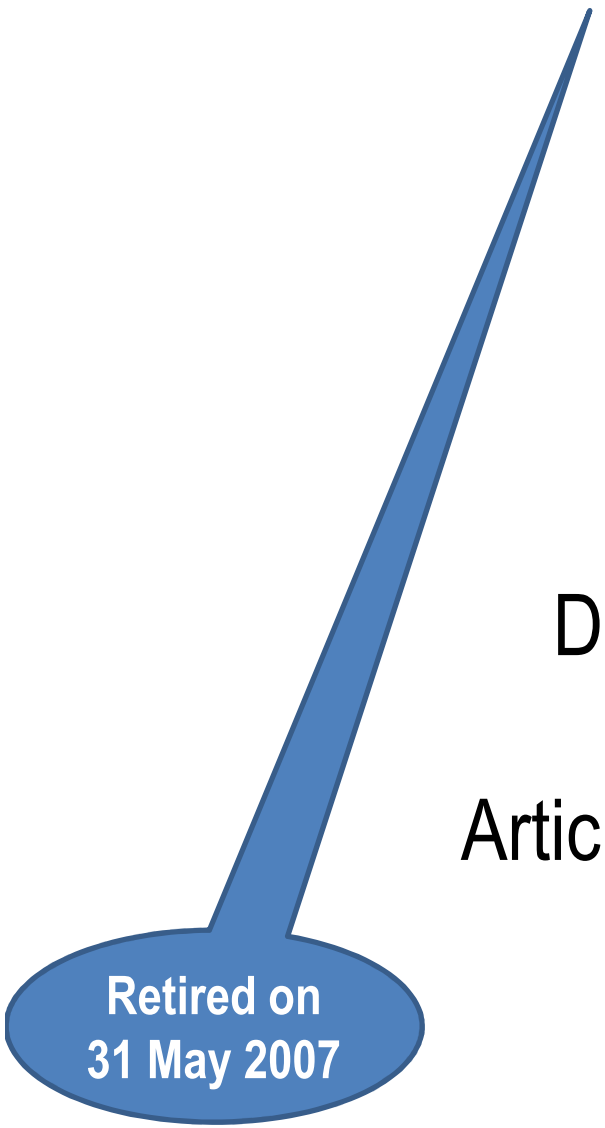
Since competition is enhanced

Since incentive is lost

Since future innovation would be threatened

Satwant Reddy Committee

Report
On
Steps to be taken by
Government of India
in the context of
Data Protection Provisions
Of
Article 39.3 of TRIPS Agreement
31st May, 2007



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'new chemical entity', 'considerable effort' and 'unfair competition'

Mentioned but not defined

Hence flexibility in interpretation

Data protection possible in two potentially simultaneous forms

Trade Secret

Data Exclusivity

Two opposing arguments

No need and No obligation under TRIPS for fixed period data protection

Needed

Globalisation, China has, risk of unfair use, patented and non-patented, fakes

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Different requirements of data protection in different fields

Pharmaceuticals

Drugs and Cosmetics Act, 1940 and Rules, 1945

Doha Declaration Part 4

Amendment of Article 31 (f) of TRIPS *re* compulsory licence by exporting country

Traditional Medicines

Drugs and Cosmetics Act, 1940 and Rules, 1945

Efficacy and background data reliance on classical texts

Agricultural Chemicals

The Insecticides Act, 1968

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Protection in other countries

Exclusivity

USA : 5 years – Pharmaceuticals (+3 for new indications), 10 years – Agro-chemicals

EU: 10 years – Both (+1 for new indications)

Canada: 8 years for both

Japan: 6 years for both

China: 6 years for both

Brazil: Only Agro-chemicals

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Recommendations

Traditional Medicines – Fixed period of 5 years

New use or new dosage

Standardisation of products

Safety or efficacy or stability or quality or process standardisation

Satwant Reddy Committee

Recommendations

Pharmaceuticals

Long term benefit for India in higher standards of protection

Divide period into Transitional and Post transition

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Recommendations

Transitional Period

Only minimum obligations under 39.3 to be met

Applicants to declare trade secret that needs protection

DCGI obliged to keep such undisclosed information secret

Fraudulently obtained data in later applications to be treated as unfair commercial use

Non-disclosure agreements with leaving employees

Spell out liability of use of data by third party without consent

Central Government to have power to disclose trade secret under exceptional circumstances

Define ‘several years’ under D&C Rules for drugs approved and marketed abroad

Data management recommendations

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Recommendations

Post -transition

Use definition of a new drug under Rule 122 E of D&C Rules as that for NCE

or

Use a new definition

"A drug based on a new chemical entity which had no prior application for approval of the same drug in India or where the same drug or chemical entity was not previously known to commerce."

However, exclude – new indications, new dosage, new combinations, 3(d) items

5 years of data protection to proprietary test data given by **Originator**

No final approval for subsequent applicants using same data

Exemptions

Drugs for life-threatening diseases like HIV-AIDs

Satwant Reddy Committee

NSG's views – Annexure 2

Certain other points made which were considered by the Committee

Mandatory provision for ensuring the safety and quality of drugs

Power of the DCGI to demand undisclosed information for drug approval for manufacture or import

Limit the data requirement to new drugs that are introduced first in India and not available in the market anywhere in the world

Liability of persons in the office of DCGI under the Official Secret Act, 1923

Centre for WTO Studies
विश्व व्यापार संगठन अध्ययन केन्द्र

Thank you

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IP Enforcement and Access to Medicines

K M Gopakumar

Third World Network (TWN)

9 October 2009

Outline of the Presentation

- Enforcement under the TRIPS Agreement
- IP Enforcement : Emerging Scenario
- WHO and IP Enforcement
- Structure of IMPACT
- IMPACT Outcomes
- Issues of concern

What is IP Enforcement

- IP rights are private rights
- General remedy : Civil Suit
- Exceptional case: Criminal Remedy
- Mechanisms for IP Enforcement
  - Administrative mechanisms (Customs, Police)
  - Judicial mechanisms
- State Enforcement : Use of public Money for the enforcement of private right

IP Enforcement under TRIPS

- TRIPS Agreement prescribes minimum standrads
  - IP protection standards
  - Enforcement standards
- Enforcement of IP under TRIPS
  - Civil procedure
  - Border measurers
  - Criminal procedure only for the commercial scale infringement of trademark and copyrights

TRIPS : Preamble

- ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade; (Preamble)
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems; (Preamble)

TRIPS: Objectives

- The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

General Obligations on Enforcement

- Avoid creation of barriers to trade
- Fair and equitable procedure
- Reasoned and writing decision
- Opportunity of review of administrative and judicial decisions
- No obligation to create special courts
- No obligation for resource allocation for IP enforcement

Specific Obligations

- No compulsory injunction in case of Government use
- Damage is within the judicial discretion
- Judiciary has also the authority to order expense to the right holder
- Criminal remedy in case of willful trademark counterfeiting or copyright piracy on a commercial scale.

Border Measureres

- Mandatory to apply in case of importation
- Optional in case of export goods
- Applies only in case of trademark and copyrights
- Initiated upon the application of right holder having valid grounds to suspect to the udicial or administrative authorities

…Border Measures

- Compensation to the importer incase of wrongful detention
- Ex officio actions are optional
- De Minimums imports are exempted

TRIPS Plus Standards on Enforcement

- New concept of IP Infringement and its criminalisation
- Special administrative unit
- Special courts
- Special IP enforcement units within police and customs
- Legal reconnection of private sector enforcement
- Enhancement of damage and penalty

TRIPS Plus Standards on Enforcement

- Separate legislation (Anti counterfeit)
- Treating infringement of IP as a crime
- Separate agency for the enforcement of IP

TRIPS Definition of Counterfeit

- counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

New Concept of Counterfeit and Piracy

- “are used to describe a range of illicit activities linked to intellectual property rights infringement . The work that the OECD is conducting focuses on the infringement of IPRs described in the WTO Agreement on Trade Aspects of Intellectual Property Rights . It includes trademarks, copyrights, patents design rights, as well as a number of related rights”

TRIPS Plus Border Measures

- Covers all IP rights including patents
- Applies to exportation , re–exportation, entry or exit of customs territory-Goods in Transit (EU)

  For e.g. Seizures of medicines in EU 17 seizures in 2008 in Netherlands.
- Mandatory ex–officio action (Japan)
- No exception to de-minimums

IP Enforcement : Emerging Scenario II

- Domestic initiative
- Bilateral agreements
- Free Trade agreements (FTAs)
- Plurilateral negotiation (ACTA)
- Multilateral organisations
- Regional initiatives

IP Enforcement and FTAs

- Expands criminal remedy to patents (Japan)
- Compulsory damage (EU)
- Pecuniary damage (EU)
- Expands the scope of injunction against intermediaries whose services are used by a third party to to infringe an IPR (EU)
- Interlocutory injunctions (EU)
-

IP Enforcement and FTAs

- Compulsory payment of legal cost to un successful party (EU)
- Obligation to disclose information on intermediaries (EU)

Multilateral Initiatives

- WCO –SECURE
- UPU
- WHO-IMPACT
- INTERPOL-IP Crime Unit
- WIPO-Advisory Committee on Enforcement
- WTO- TRIPS Council Request

WHO and IP Enforcement

- Projecting counterfeit drugs as a public health issue
- New initiative 2006 : International Medical Product Anti-Counterfeit Taskforce (IMPACT)
- WHA Resolution on counterfeit medical product (May 2008)

IMPACT: Structure

- A multi-stake holder initiative with govt. institutions, international organizations, private sector and civil society organisations (WCO, Interpol)
- General Meeting
- Planning Group
- Working Group
- Secretariat : WHO

IMPACT: Major Outcomes

- Principles and elements for national legislation against counterfeit medical products
- Text proposing revisions to WHO good distribution practices
- Best practices for pharmacists and other healthcare providers for updating the FIP/WHO Good pharmacy practices (GPP)
- Guide to investigating counterfeit medical products and other pharmaceutical crime
- Anti-counterfeit technologies for the protection of medicines

Issues of concern I

- Private sector driven international norm setting
- Non transparent and non participatory international law making
- WHA Draft Resolution

  to establish and enforce legislation and regulations that prevent counterfeit medical products to be manufactured, exported, imported or traded in international transactions and the regulated distribution system, taking into account the principles and recommendations developed by the International Medical Products Anti-Counterfeiting Taskforce

Issues of Concern II

- IP Enforcement agenda

"*Trade in pirated and counterfeited goods threatens health, safety and security of consumers worldwide particularly in poor countries. In this regard we welcome work on the WHO initiative to implement international medical product anti-counterfeiting Taskforce (IMPACT)*

…Issues of Concern II

- *"Efforts to protect public health from injury associated with counterfeit goods can complement and augment strategies to protect intellectual property rights. The fact that some interventions protect intellectual property rights does not negate their importance to the protection of public health and safety* (Michele Forzley, Counterfeit Goods and the Public's Health and Safety Counterfeit Goods and the Public's Health and Safety)

Issues of Concern III

- Expanded the scope of counterfeit definition

*"The term counterfeit medical product describes a product with a false representation [(a)] of its **identity** [(b)] and/or **source**[(c)]. This applies to the **product**, its **container or other packaging or labelling information**. …"*

…Issues of Concern III

- *Violations or disputes concerning patents must not be confused with counterfeiting of medical products*

Issues of concern IV

- NTBs
- Entry barriers
- TRIPS Plus enforcement measurers

…Issues of Concern IV Examples

- Establish liability of Internet Service Providers
- Regulate manufacture of active substances and of certain experiments that may pose public health risks
- Regulating international trade of labels and packaging materials for medical products

Seizure of Goods in Transit

- 17 seizures of medicines in transit in 2008 alone in Netherlands alone
- Action is taken under the EU Regulation of IP Enforcement
- It violates TRIPS Agreement

IP Enforcement in India

- TRIPS Plus Border Measures
- Liberal issuance of preliminary injunctions
- FTA engagements
- Conflicting stand in multilateral foras
- Vested interest among apex trade bodies

Implications for A2M

- Compromises access to medicines in India and other developing countries
  - Affects through the strong enforcement provisions on trademark and patents
  - Criminal remedy against patent infringement
  - Border measures on exports
  - Border measures on de-minimums
  - Expanded scope of injunctions i.e against intermediaries thretns bulk drug supply

INTRODUCTION TO PATENT LAW

- Scope and Rationale
- Subject Matter
- Novelty
- Non-Obviousness
- Utility
- Procedure to File a Patent

Scope and Rationale

- A patent is the grant of the exclusive right to protect an invention by ensuring that no other person may make, use, distribute or sell any commodity which uses this product or process.

- *Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries* ((1979) 2 SCC 511), held that "the object of patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive privileges to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after expiry of the fixed period of the monopoly, passes into the public domain."

Sources of Patent Law

- The sources of patent law are the national laws on the subject and no global or international patent law exists. This is not to say that there is no existing international legal framework.
- The multilateral treaties which seek to harmonize the law of patents are –

1. Substantive patent law: Paris Convention, 19679 and the Trade Related Intellectual Property Rights Agreement, 1994 (better known as the TRIPs Agreement). Most recently, countries across the globe are trying to reach a consensus in relation to the Substantive Patent Law Treaty (SPLT).
2. Procedural patent law: Patent Law Treaty, 2000 and the Patent Cooperation Treaty, 1970, which provide for the maximum formalities in the application procedure and a unified international application process respectively.

The Criteria of Patentability

- Article 27 of the TRIPs Agreement stipulates that in order to be granted a patent the invention must involve an inventive step, be capable of industrial application and should not fall within the specified categories of excluded subject matter.
- The logic behind stipulating these criteria for granting patent protection was made clear in as early as 1883 by Justice Bradley in his decision in *Atl. Works* v. *Brady* (107 U.S. 192 (1883)), wherein he stated that:

"The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge and makes a step in advance in the useful arts. Such inventors are worthy of all favor. It was never the object of those laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures. Such an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention."

Subject Matter

- Article 27 of the TRIPs and Sections 3 and 4 of the Indian Patents Act deal with these criteria.

- In relation to pharmaceutical products three kinds of exclusions are relevant:

(a) Inventions which violate the ordre public or morality of a member state including to protect human, animal or plant life or health or to avoid serious prejudice to the environment;

(b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(c) 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.

Subject Matter II

- Section 3(d) renders '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 a 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'.
- In light of the judgment of the Madras High Court *Novartis* Case the expansive scope of the Section 3 exception has been sustained as far as domestic law is concerned.

Subject Matter III

- The list of non-patentable subject matter provided for in these provisions is exhaustive in nature as there is no express statutory wording to the contrary. However, the nature of the list is such that it is possible to interpret the grounds in a broad manner.
- Not all prohibitions provided in the provisions are absolute. For instance, a computer program *per se* is not patentable, but if embedded in a machine or chip, it may possibly be protected by patent.

Novelty

- The element of novelty requires that the invention should be a new product or a new process.
- Section 2(1)(l) of the Patents Act defines a “new invention” as any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing the patent application with complete specification, i.e., the subject mater has not fallen in the public domain or that it does not form part of the state of art.
- The novelty criterion may be assessed at the examination and opposition stage prior to the grant of the patent, or the revocation stage post the grant of a patent.

Novelty II

- The essence of the novelty requirement is encapsulated by the Bombay High Court in *Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning a Corporation etc.* v. *Unichem Laboratories and Ors.* (AIR 1969 Bom 255) where the High Court stated that, "To anticipate a patent, a prior publication or activity must contain the whole of the invention impugned; …. In other words, the anticipation must be such as to describe, or be an infringement of the claim attacked."
- A finding of novelty is dependent upon the state of prior art, i.e., the existing state of knowledge in the particular field and the two broad sources for the determination of state of the art are prior knowledge or use and prior publication.

Novelty III

- India has mixed novelty, as opposed to local or absolute novelty. Mixed novelty is in relation to what constitutes prior art for the purposes of a particular invention. Anticipation by prior public use and prior public knowledge is limited to such prior use and knowledge in India. On the other hand, anticipation by publication has an absolute novelty standard, i.e., the invention should be novel and not be anticipated by prior publication anywhere in the world.
- As regards anticipation by prior public knowledge and prior publication, it should be noted that for such information to form a part of the state of the art there is no need for the information to be put to actual use. The mere fact that it was available and capable of being used by the public, that is, an unrestricted group of people, is sufficient.

Non-obviousness

- This criteria mandates that, even if there isn't a specific prior art source anticipating the invention, prior art sources taken together also should not anticipate the claimed invention.
- The difference between novelty and obviousness is that the former requires an invention to be quantitatively different from the information disclosed earlier whereas the latter is a qualitative requirement to ascertain whether the contribution is creative enough to warrant a monopoly.
- Article 27 of the TRIPs Agreement lists out the requirement of non – obviousness or inventive step as does Section 2(1)(j) of the Indian Patents Act.

Non-Obviousness II

- The process of determining the existence of an inventive step has been accounted for in the Indian Patent Manual (2005). The patent examiner must:

1. Examine the scope and content of prior art.
2. Ascertain the difference between the prior art and claims at issue.
3. Resolve the level of ordinary skill in pertinent art.
4. Determine the obviousness or non-obviousness of the subject matter against this background.

Non-Obviousness III

- Does mere economic significance of a claimed invention, in the absence of any technical advance, constitutes an inventive step?
- *Bishwanath Prasad* v. *H. M. Industries* (AIR 1982 SC 1444).
- V.J. Taraporewala
- Shamnad Basheer

Utility

- The phrase “capable of industrial application” implies usefulness or utility.
- Utility in patent law does not mean either “abstract utility, comparative utility, competitive utility, or commercial utility”.
- Section 2(1)(ac) defines “capable of industrial application” in relation to an invention, to mean that the invention must be capable of being made or used in an industry. Lack of capability of being used in an industry is a ground for revocation of the patent under Section 64(1)(g).

Utility II

- What is the quantum of utility required to support a patent?
- In the absence of any promise in the specification that a definite degree of advantage would result from the use of the invention, the amount of utility to support a patent is very small. The test is whether the new method “gives the public a useful choice”.

Procedure for Filing for a Patent

1. Submission of application.
2. Examination of application.
3. Advertisement of acceptance of complete specification.
4. Opposition to grant of patent to the applicant.
5. Hearing of the parties.
6. Grant and sealing of the patent.

IPRs and Alternate Incentives for Pharmaceutical Innovation: CIPIH, GSPOA and Beyond

Dinesh Abrol, NISTADS

School for Trade & Public Health, CENTAD, October 8, 2009

Evolution of heuristics of pharmaceutical innovation

- **New drugs generated within path-dependent socio-technical systems based on heuristics embedded in distinct & hierarchies of interconnected operating principles that structure the way problems are solved**
  - 19th century extractive heuristic; simultaneously spurred by patent protection; synthetic chemistry used to improve the performance of natural alkaloids, in parallel, biological heuristic –Koch & others developed anti-toxins from serum extracted from animals exposed to bacterium
  - During the post-WW II period the plant based heuristic / biological traditions waned as a synthetic chemistry heuristic provided the industry with a “golden age” of productivity driven by random screening of synthetic compounds. Within this heuristic firms exploited their capabilities in medicinal chemistry; this is where CSIR labs & Industry worked in India & have capabilities
  - By the 60s the productivity of molecular roulette began to decline. Improved characterisation of drug receptors still realised (the protein targets on which many drugs act) allowing directed screening & improved productivity, reduced the no. of costly exp cycles. However, during the age pharmacologists still knew little of molecular structure of their targets

Continued

- Emergence of guided screening-the 70s saw a shift towards generating knowledge about the structural properties of drug-target interaction to guided screening, birth of rational drug design which became biology intensive, preceding work on proteomics; academic community used by industry to get insights into biological pathways, often natural inhibitors providing direction, with drug discovery driven by research industry now could direct work profitable chronic diseases
- Scope opened by ration drug design heuristic created industrialization of research, no more dependent on traditional static economies of scale & scope in production; moved towards dynamic economies of scale & scope;
- Revival of biological heuristic through guided screening & rational drug design used to extend the utility of synthetic heuristic; in parallel the development of genetic engg & monoclonal antibodies in the late seventies revived the biological heuristic providing new operational principles; toolbox of restriction enzymes, vectors & cell culture methods made available
- Molecular biologists learnt how o cut & splice genes, express protein products in scalable volumes & started generating new variants; emergence of biotech sector potential of these techniques recognised by academics & VCs in early 80s led to the formation of a wave of biotech firms; recombinant insulin –a joint outcome of gentech & Eli Lilly Gentech & Amgen
- Advent of genomics, small biotech, new IP regime, financialisation of biotech, Challenge from late industrialising world pharmaceutical industry targeted through trade negotiations
- In parallel, role of changes in institution of science & impact of IP , failures experienced, decline in productivity, saturation of low hanging fruits, pharma focusing on riskier, genomics based candidates rather than clinical validated drug targets, pharma too big to innovate, IP regime creating barriers

Pre-TRIPs Story of Pharmaceuticals in developing countries

Stage of development in the beginning of 90s	Number of Countries		
	Industrial	Developing	Total
Sohpisticated pharmaceutical industry with a significant in-house research base	10a	0	10
Countries with innovative capabilities	12	4b	16
Those producing both bulk drugs and formulations	6	8	14c
Those producing only formulations	2	87	89
No pharmaceutical industry	1	59d	60
Totals	31	159	190

a (United States, Japan and 8 countries in Western Europe)

b Argentina, China, India and Mexico

c European and higher income Latin American Countries (e.g., Brazil) and Asian countries

d primarily African countries and small islands

Source: Balance, Pogany & Forstner 1992, The World's pharmaceutical industries: An international perspective on innovation, competition and policy, Ashgate Publishers, Brookfield, VT.

Pharma's existing strategies for improving R&D productivity

- Innovation gap responded in terms of increased R&D spending to horizontal consolidation, biotech in-licensing, consequently decreased profitability of pharmaceutical firms
- New strategies & models for improving R&D productivity; CROS providing drug discovery services (chemistry, biology, screening & lead optimization; drug discovery research follows development outsourcing; more mature is drug dev outsourcing, changing role of in-house capabilities; high risk & high cost of new platform technologies
- Consequences for efficient learnig, Asian outsourcing & IP, cultural & communication barriers, CROs being asked to share risk, bridging of cultural & communication barriers & strategies for limiting risk in Asia by increasing their stakes in Asia; innovation through pathway development
- Discovery services provided by CROs; **Biology services** (protein expression & purification, protein structural analysis, determining protein-protein interactions, functional genomics, bioinformatics); **Chemistry services** (providing building blocks, compound synthesis & purification, process development, library design); **Screening services** (assay development, secondary screening); **Lead optimization services** (ADME / Toxicity, compound analogues & structure activity relationships)
- PCR / Micro-arrays, historically cooperative platform technology development have spawned out of biotech start ups & academia.
- Academia incentive structure & culture; are biotech start ups an answer;

Evolution of new models of innovation

- Big pharma trying to address the untapped innovation space through automation, evolving complexity requires significant complementary assets, tech taking 10 yrs to perfect, developing interdisciplinary large team based effort; forming semi-autonomous technology innovation consortium (Howard Hughes Medical Institute creating Janelia Farm with culture for multi-disciplinary work culture & incentives)
- Open source innovation; sharing of information in an incremental, cumulative fashion across companies, institutions, areas of expertise & platforms of research; individuals contribute their efforts to commons or public domain, harnessing of IT & application of open-source extended to public-private partnerships; Benefits of creativity, speed, risk sharing, , agility, affordability---vis-à-vis economic barriers arising out of incentive structures.
- Potential solutions; can RIs / Universities coordinate open-source, the question of mobilization of resources from private sector ; coordination & leadership barriers being solved through PPPs; but these models do not offer good solutions to type II & III diseases,
- Separation of monopoly pricing from product development remains a challenge. Regulation & IP Challenge is huge even in developed countries.
- Motivation & availability of talent, methods being used in OSDD, open source bioinformatics initiatives, solutions in MMV open calls, voluntary publication of fundamental knowledge, informal clinical trials through field discovery; clinicians involved in open source trials (User innovation model), user innovation model applied to drug discovery
- Medical innovation prize fund, bills & treaties are under consideration

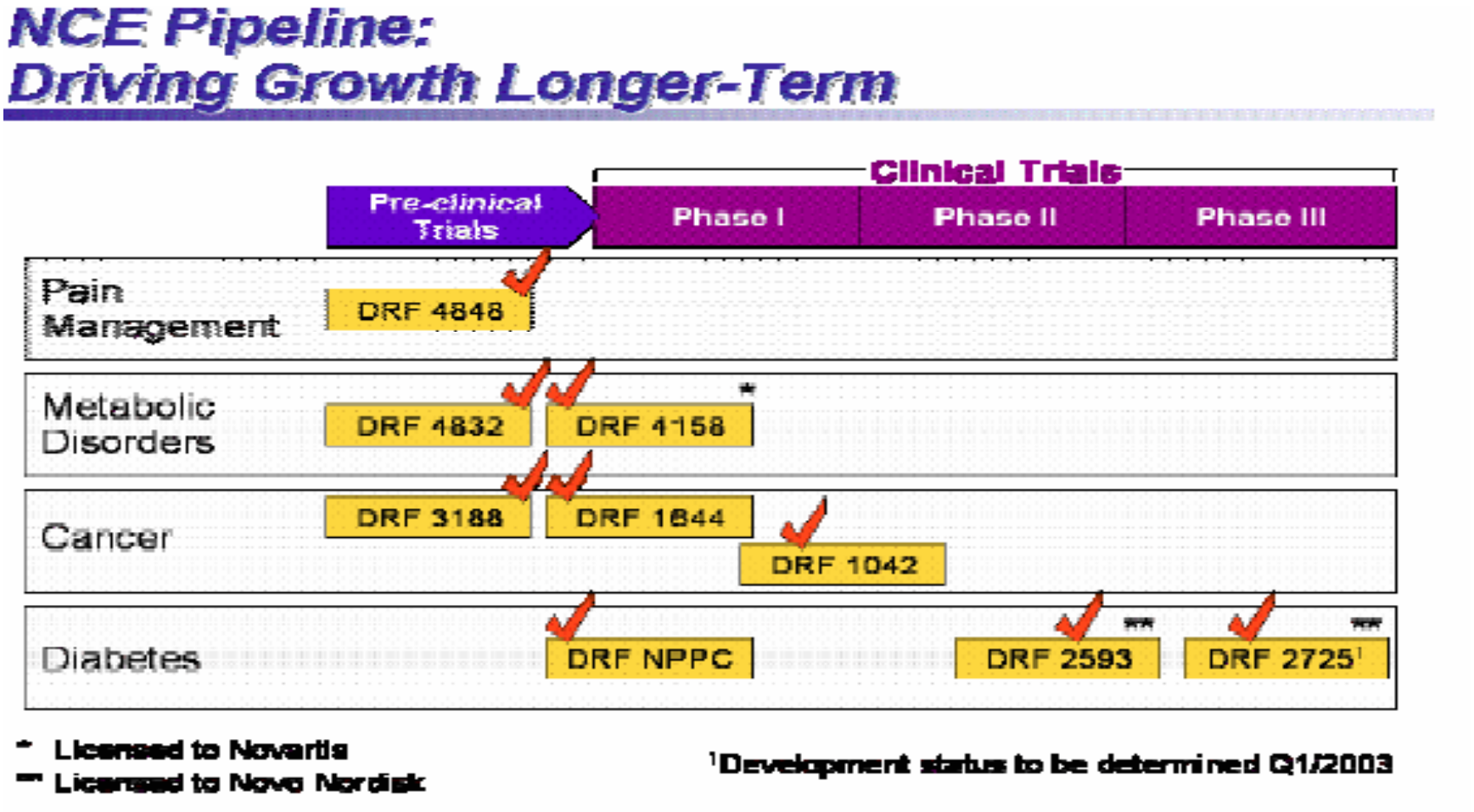
R&D for development of new drugs for neglected diseases

- Out of 2257 new drugs introduced during 1981-2000, only 7 (0.31%) were major innovations where previously no treatment was available, 67 (2.5%) important inventions, 192 (8.5%) products with value but didn't change the therapeutic practice Prescrire (2001).
- No increase in R&D by MNCs on diseases of the poor
- Pradhan (2003) reports 0.74 % as R&D intensity of foreign firms; 3.5 times lower than domestic firms' R&D intensity.
- Updhyaya, Ray & Basu (2002) report on the thrust of MNCs R&D being limited to formulation R&D and not on product development; no research on NDDS.

Nature of technological accumulation in pharmaceuticals

- Emerging patterns of technological accumulation
  - Patterns of integration for global R&D by MNCs indicate little social benefits.
  - A handful of Indian firms have been able to increase their R&D investments in product R&D for lifestyle diseases.
- Emphasis on non-essential & elite pattern at the level of both manufacturing & R&D.
  - even the government initiatives subordinate themselves to big business interests

Pattern of product development in DRL



Changing pattern of industrial & product structure in pharmaceuticals

- Emerging patterns of industrial transformation
  - Indian firms opting for non-innovative bulk drug outsourcing.
  - Export of generics paved with hurdles of costly patent litigation, drug safety regulation used for monopoly enhancement, Para IV filings / biogenerics.
  - Potential for innovation & competence building through the export of generics is limited.

MNCs offering donation of IP rights

- Companies / universities / institutes donate IP rights to government / consortia
- Drugs can be priced near cost of production; good publicity for donors
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, no incentive to address needs of LDCs, or no incentive to address type II and III diseases, not economically self-sustaining
-

Universities donating IP rights

- Universities donate IP rights to not-for-profit drug developers (e.g., One World Health)
- Drugs can be priced near cost of production; good publicity for donors
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, no incentive to address needs of LDCs, or no incentive to address type II and III diseases, not economically self-sustaining

Encouragement to big pharma industry to set up dedicated units

- Companies set up R&D units dedicated to type II and III diseases: e.g., GlaxoSmithKline in Tres Cantos, Spain; AstraZeneca in Bangalore, India; Novartis Institute for Tropical Diseases in Singapore; or devote resources, internally (Johnson & Johnson, Otsuka, Bayer)
- Innovation anticipated; good publicity for companies
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, not economically self-sustaining, does not address problem of access

Government increases biomedical research & places IP in public domain

- Government doubles support for biomedical research, devotes the increment to drug R&D at publicly funded research corporations with patents placed in the public domain
- Might lead to more drugs at lower prices
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, politically objectionable

Government increases drug R&D, cos forgo monopoly through treaty

- Governments pay for a larger portion of drug R&D in government, academia or drug companies; recipients forego monopoly; costs met from mandated contributions by individuals or employers or by governments by treaty
- More public funding for R&D; governmental rather than private choice of targets; lower prices
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, no incentive to address needs of LDCs, Insufficient experience in or failure to include one or other critical stage of drug development

Institutes / University scientists are encouraged to work on type II/III

- Universities conduct R&D for type II, III diseases with help from government and philanthropy to include medicinal chemists
- Examples exist; provides academics with facilities like those at small biotech companies
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, not economically self-sustaining, does not address problem of access, Insufficient experience in or failure to include one or other critical stage of drug development

Public-private Partnerships

- PPPs (philanthropically funded) use contracts to manage drug development at diverse sites in biotech or pharma
- Professionally managed without profit drivers; efficient distribution of tasks among contractors near cost
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, not economically self-sustaining, Insufficient experience in or failure to include one or other critical stage of drug development

Tax incentives

- Tax incentives favor R&D for high medical need and can be invested or traded
- Encourages innovation
- Shortcomings: no incentive to address needs of LDCs, or no incentive to address type II and III diseases, does not address problems of access

Orphan drug act

- Extend Orphan Drug Act to cover type III diseases (fast-track approval, 7-year extended market exclusivity, 50% tax credit on clinical trials)
- Has led to many new drugs in what would otherwise be financially unrewarding markets
- Shortcomings: no incentive to address needs of LDCs, or no incentive to address type II and III diseases, does not address problems of access, has led to high prices, has not attracted most large firms

Patent extension

- Patent extension for producing drugs for type II and III diseases
- Encourages innovation
- Shortcomings: No incentive to market, distribute, improve, does not address problems of access, politically objectionable, only attracts firms holding lucrative patents, increases costs for other drugs

Purchase commitments

- Advance purchase commitments
- May lead to new products
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, No incentive to market, distribute, improve, governments heavily influence which drugs will be widely used d,difficult to assign fair value, does not improve access to existing drugs, uncertainty in ability to meet specifications, winner takes all rewards are disincentives, race to the finish discourages risk-taking science, without which there may be no effective product

Differential pricing

- Differential or Tiered pricing
- Improves affordability to some users; already in widespread use with relatively narrow differentials
- Shortcomings: no incentive to address needs of LDCs, or no incentive to address type II and III diseases, does not address problems of access, politically objectionable, governments heavily influence which drugs will be most widely used

Consortia & patent pooling

- International pooled purchasing consortia
- Negotiates lower prices
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, no incentive to address needs of LDCs, or no incentive to address type II and III diseases, not economically self-sustaining

CL

- Compulsory licensing to permit patent violation by a producer who sells
- at lower cost
- Improves affordability to some users
- Shortcomings: no incentive to address needs of LDCs, or no incentive to address type II and III diseases, not economically self-sustaining, no centive for improvements, backflow of drugs from low-price from low-price to high price regions

Choices within TRIPS

- Obligatory choice of protecting patents in either rich or poor countries, not both
- Lowers cost of drugs for type I diseases in less developed countries; encourages in-country production
- b,c,e,h

Prizes

- Buyout or prize system (government provides patent holder its profit)
- Improves affordability
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies, a,d,i,j

Patent buy outs

- Patent buyouts by auction
- Allows lower pricing
- Shortcomings: Limited coverage by disease, or limited involvement of scientists, companies no incentive for improvements, govts. determining widely used drugs

a,d,i,j

New dedicated institutions

- Conduct R&D in new sites funded by government, universities, NGOs and pharma, with distribution at cost in poor areas and for profit in wealthy areas
- Allows R&D for all diseases or approaches lacking market drivers
- Not economically self-sustaining

Track II system

- Reward global disease burden reduction from a government fund, for example, by ‘track II’ patent registration
- Encourages R&D for high medical need; governments and insurers have experience with DALYs in including drugs in formularies, fall in drug prices would save money for government, business
- Initially, not economically self-sustaining, difficult to assign fair value

A New System of Rewards

- Open-access patent system track which aligns incentives with medical need
- Choosing this track would be voluntary, COs allowed to switch products of type II & III diseases, Governments of ICs and LDCs make multi-year financial commitments from which owners of a registered patent would opt to be paid periodically in proportion to reducing the global burden of disease. Contribution to be assessed on the basis of impact on QALY, benefit or payments could be extended beyond 20 years, compete for ongoing payment possibility by product improvement, royalty free licenses, cos profits, govts pay optimally

Immediate agenda of engagement

- Burden of disease is growing in an extremely demanding way for India
  - with life style diseases of both rich and poor getting added to the existing load of problems of need to provide treatments for communicable infectious diseases to a huge mass of people
- Requires a two fold agenda of
  - On the one hand, solving problems connected with deficient medical infrastructure, removal of imbalances arising between prices & ability to pay
  - Dealing with the absence of a system of innovation capable of providing treatments for emerging & existing diseases
- Policy design for the latter agenda is the focus of policies for science & innovation.

The challenge of shaping of the process of engagement on alternate incentives

- India developed a domestic pharmaceutical industry due to enactment of a balanced patent policy in early seventies
- TRIPS Agreement involved negotiations not only with major powers but also controversy at home
- Both industry & people were participants
- Academic discourse on the pros & cons of acceptance of TRIPS played its role.
- Policy choices were shaped by the engagement process w. r. t. policies for patents, innovation & science.
- Challenges of latecomer development under globalization are at the centre of debate on alternate incentives.

CIPIH & GSPOA

- Evidence from India on pharmaceuticals is beginning to be gathered; it is still piecemeal
- In the meanwhile action has been initiated in the forum of WHO for a systemic approach to policymaking for drug innovation for neglected diseases.
- Evidence from work in making on GSPOA for public health, innovation & intellectual property.
- Preliminary report submitted to MOH & FW and WHO, India office.
- Subsequent slides report major findings & the challenge of GSPOA

Contours of the Indian divide on TRIPS & liberalization

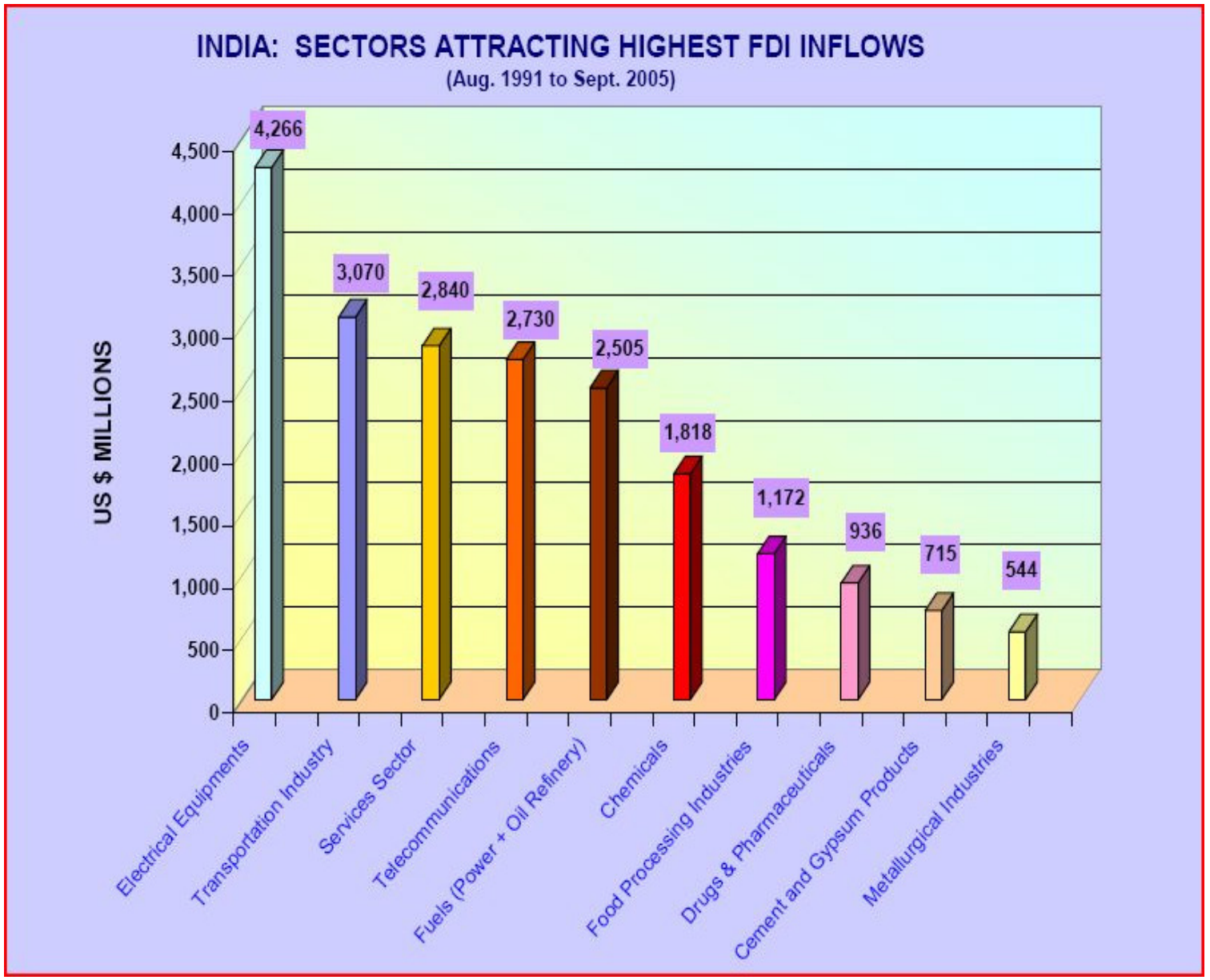
- Strong IPRs, liberalisation & neo-liberal globalization would make domestic firms move away from imitation & allow competition to improve access
- Stage of development based understanding demanded a rejection of strong IPRs & liberalisation; balanced IPRs essential for access to essential medicines
- Arguments on the pathways to be taken for the development of pharmaceutical industry were focused on the actual import of self-reliance and domestic control for access vis-à-vis global pharma offering increase in introduction of new medicines, FDI, TT & R&D.

How the Indian divide on TRIPS was created?

- Although academic discourse held that the influence of IPRs on FDI & TT was a priori ambiguous & demanded empirical verification, but the interested parties made the policymakers take a view that strong IPRs & liberalisation would enable India to upgrade pharma industry via FDI, TT & R&D
- Luring of the policymakers through the gain of opportunities emerging w. r. t export of generics & building of innovation capabilities via contract manufacture & R&D
- Academia-RIs-industry collaboration would grow & allow industry to undertake product innovation without indicating for what & whom.
- Arguments of learning & evolution of innovation capacity occurring on account the above framework tended to inform the policy approach for upgrading of the pharmaceutical industry

Current state of research on IPRs FDI, TT & R&D

- Branstetter, Fisman & Foley (2002) report increased royalty payment to the parent firms; increased flows concentrated in the affiliates of the parent firms; Zuniga & Bascavusoglu (2003) report that stronger IPRs deter knowledge exports by French firms and conclude that patent rights are linked to market power effect.
- WIPO debate on patents & ITT remains inconclusive and cautious; UNCTAD report focused on LDCs argues against strong patents; OECD report focuses broadly on the possibility of increased imports & non-resident patenting (which are more of barriers w. r. t innovation capacity building.
- Literature suggests that IPRs are only one instrument in the toolkit, depending on orientation policy advice follows in terms of strong IPRs; more empirical work is asked for.


INDIA: SECTORS ATTRACTING HIGHEST FDI INFLOWS
(Aug. 1991 to Sept. 2005)
US $ MILLIONS
4,500
4,000
3,500
3,000
2,500
2,000
1,500
1,000
500
0
4,266
3,070
2,840
2,730
2,505
1,818
1,172
936
715
544
Electrical Equipments
Transportation Industry
Services Sector
Telecommunications
Fuels (Power + Oil Refinery)
Chemicals
Food Processing Industries
Drugs & Pharmaceuticals
Cement and Gypsum Products
Metallurgical Industries

PERCENTAGE OF FDI IN VARIOUS SECTORS FROM APRIL 2000 TO APRIL 2009

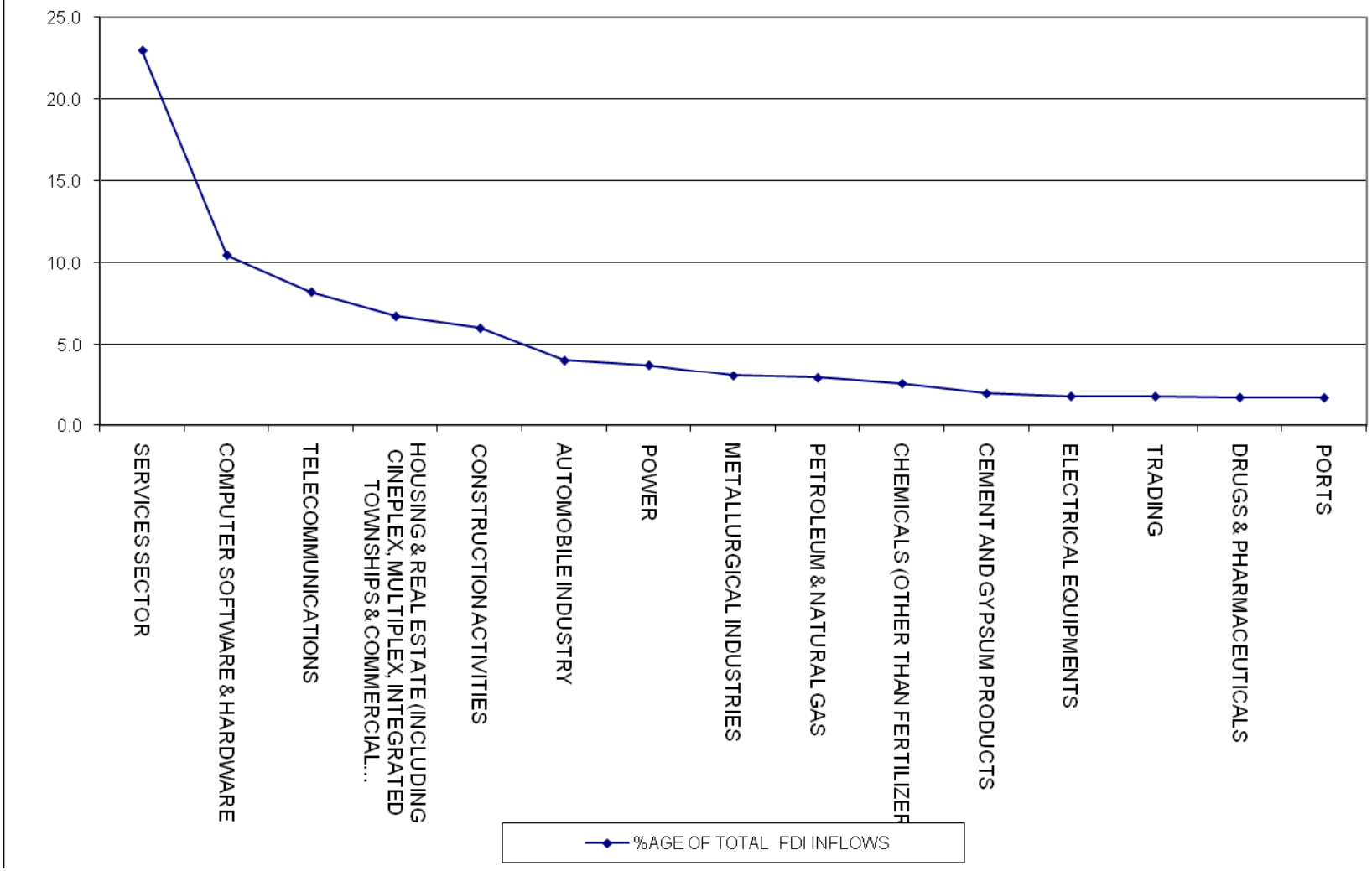
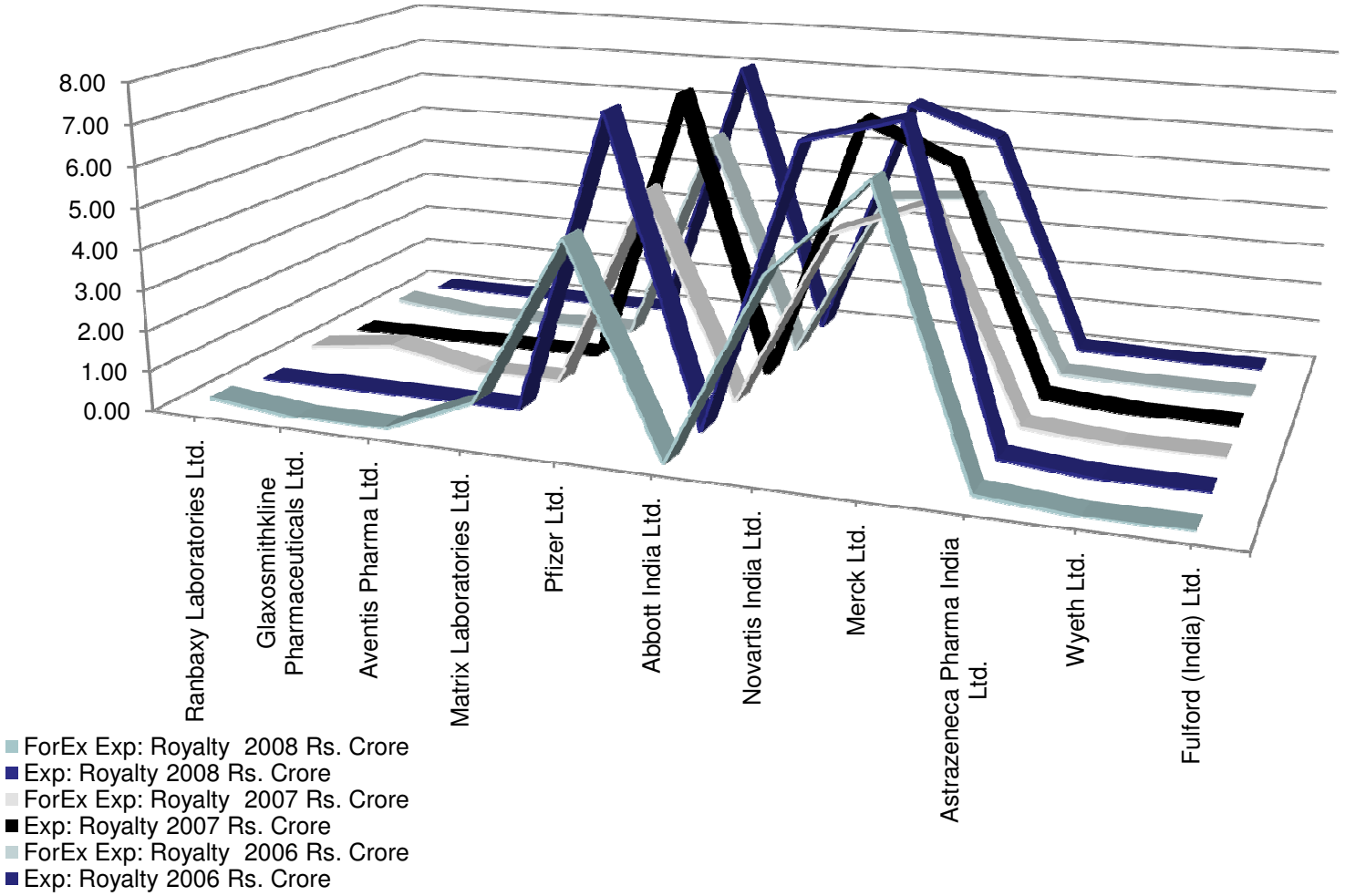


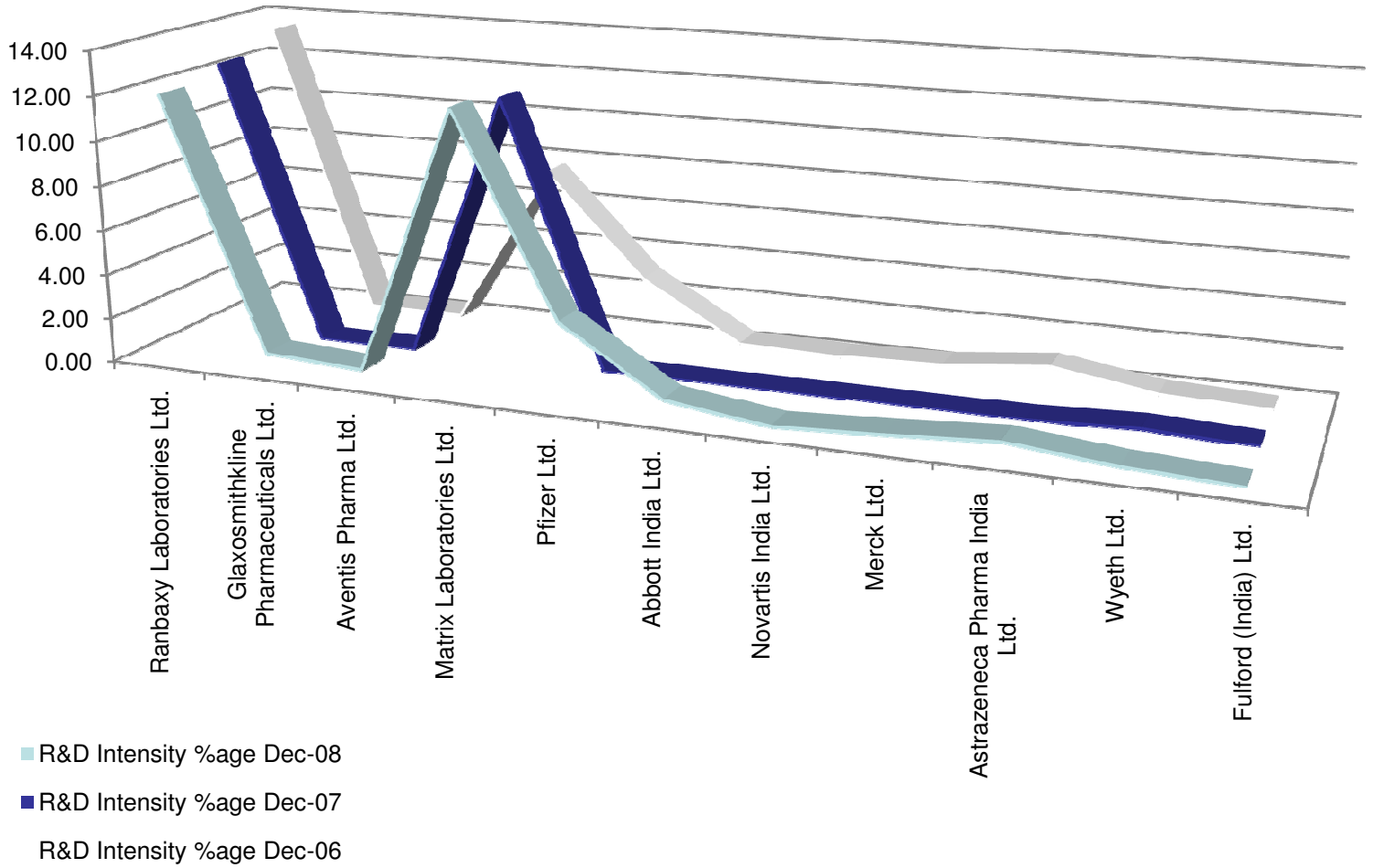
Table 2: Industry Analysis: No of Projects by Activity
Source: FDI Markets Intelligence

Business Activities	2003	2004	2005	2006	2007	2008	2009	Total	Average Annual Growth
Research & Development	2	4	10	5	8	5	2	36	44.5%
Manufacturing	3	8	6	3	3	5		28	n/a
Sales, Marketing & Support		2	2	3	1	1	1	10	n/a
Design, Development & Testing		1	1		2	1		5	n/a
Business Services			1					1	n/a
Headquarters				1				1	n/a
Logistics, Distribution & Transportation					1			1	n/a
Retail		1						1	n/a
Overall Total	5	16	20	12	15	12	3	83	42.0%

ANALYSIS OF ROYALTIES EXPENDITURE.



R&D INTENSITY.



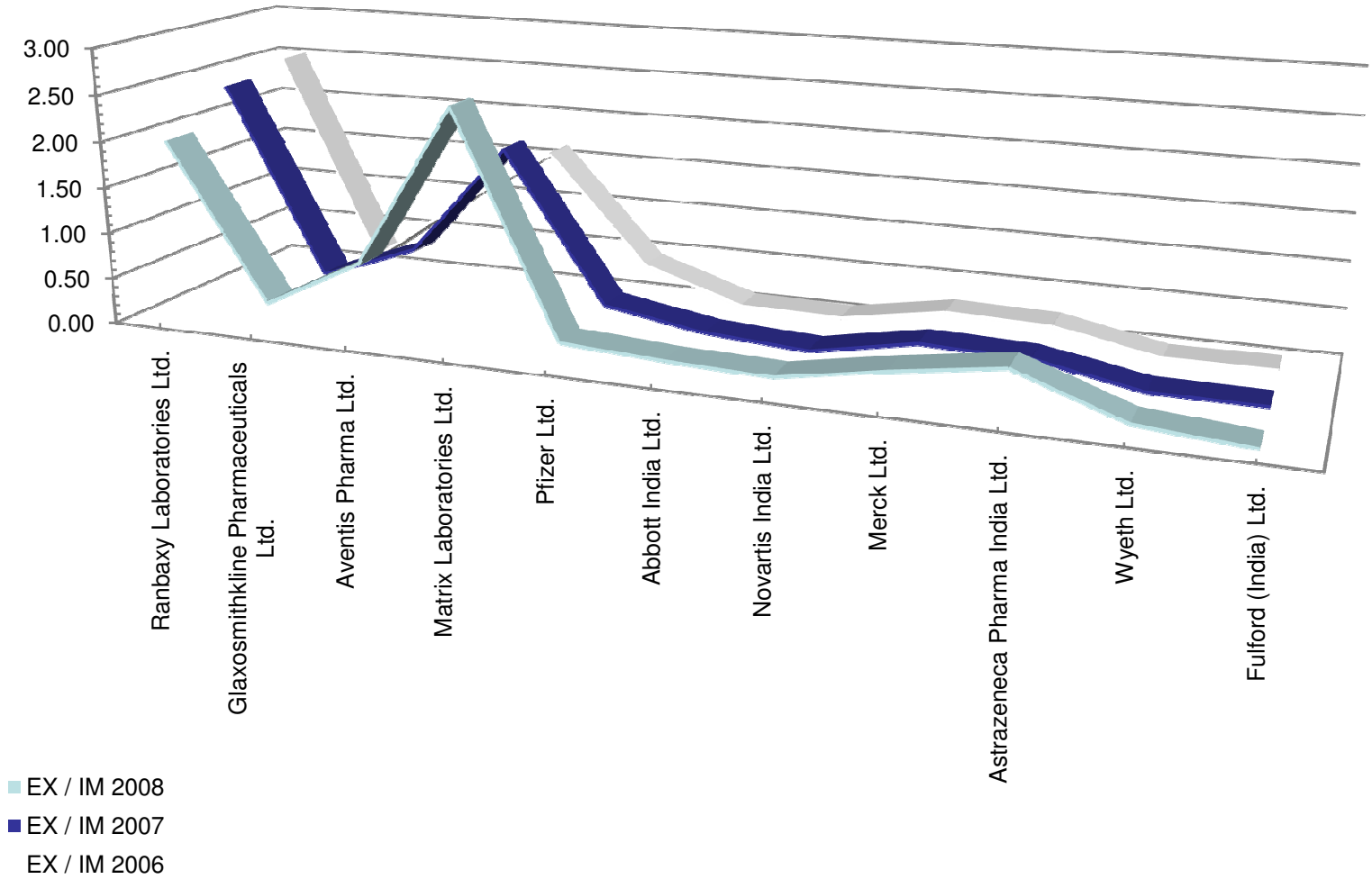
COMPARISON BETWEEN EXP ON KNOWLEDEGE ACCUMULATION AND EXP ON ADVERTISING AND MARKETING.

Company Name	Ratio: Exp Knowledge Accumulation to Exp Advertising & Marketing 2008	Ratio: Exp Knowledge Accumulation to Exp Advertising & Marketing 2007	Ratio: Exp Knowledge Accumulation to Exp Advertising & Marketing 2006
Ranbaxy Laboratories Ltd.	0.86	1.32	1.41
GlaxoSmithKline Pharmaceuticals Ltd.	0.16	0.00	0.08
Aventis Pharma Ltd.	0.11	0.00	0.08
Matrix Laboratories Ltd.	9.22	7.87	4.58
Pfizer Ltd.	0.89	0.15	0.55
Abbott India Ltd.	0.20	0.00	0.13
Novartis India Ltd.	0.28	0.13	0.21
Merck Ltd.	0.46	0.35	0.58
AstraZeneca Pharma India Ltd.	0.07	0.01	0.11
Wyeth Ltd.	0.03	0.04	0.03

Post-TRIPs Scenario: Increase in Imports based Pharmaceutical Production

- As patent strength increases IP holders find it more profitable to reserve certain markets for imports rather than direct investments: Brazil, Mexico & India
- Orsi (2003) reports the closure of 1700 production lines of synthetic intermediates during the period of the first half of 90s in Brazil.
- Combe and Zuniga (2003) reports decline in pharmaceutical firms (225 in 80s to 178 in 90s), bulk drug (259 in 87 to 105 in 98) & in chemical input supply firms from 94 in 87 to 35 in 98 in Mexico.
- India is also experiencing a restructuring based on imports & getting concentrated under global pharma, the process is still on.

IMPORT AND EXPORT STATISTICS OF FOREIGN FIRMS



India: FDI in Pharmaceuticals

- New FDI devoted to the merger activity
- MNCs shift to the imported bulk drug based formulations; investments for the expansion of formulation activity
- New operations through the incorporation of wholly owned subsidiaries
- Regulation of FDI for the encouragement of manufacture from basic stage removed from the statue under pressure from Pfizer

Changing pattern of industrial & product structure in pharmaceuticals

- Emerging patterns of industrial transformation
  - Indian firms opting for non-innovative bulk drug outsourcing.
  - Export of generics paved with hurdles of costly patent litigation, drug safety regulation used for monopoly enhancement, Para IV filings / biogenerics.
  - Potential for innovation & competence building through the export of generics is limited.

Royalty paid by domestic Firms

Cipla Ltd.	0.92	0.00	0.94
Dr. Reddy'S Laboratories Ltd.	1.19	1.22	1.42
Lupin Ltd.	0.88	0.00	0.75
Sun Pharmaceutical Inds. Ltd.	1.16	2.06	9.69
Aurobindo Pharma Ltd.	5.96	6.16	5.22
Piramal Healthcare Ltd.	0.32	0.03	1.33
Cadila Healthcare Ltd.	0.99	0.18	0.95
Wockhardt Ltd.	1.97	2.57	3.29
Glenmark Pharmaceuticals Ltd.	0.92	1.00	0.85
Orchid Chemicals & Pharmaceuticals Ltd.	2.88	2.88	3.64
Ipca Laboratories Ltd.	0.54	0.55	0.83

Post-TRIPs Contract Manufacturing Options for Domestic Industry

- Contract manufacturing as an option; Ranbaxy and Lupin were first to bag contracts; Eli Lilly involved Ranbaxy to produce intermediate for Cefaclor after it discovered an alternate process.
- Nichlos Piramal entry into CRM operations require it to forge JVs with Allergan & Baker Norton
- CRM useful, but inadequate for upgrading of capabilities needed for the development of complex & innovative manufacturing.

Nature of technological accumulation in pharmaceuticals

- Emerging patterns of technological accumulation
  - Patterns of integration for global R&D by MNCs indicate little social benefits.
  - A handful of Indian firms have been able to increase their R&D investments in product R&D for lifestyle diseases.
- Emphasis on non-essential & elite pattern at the level of both manufacturing & R&D & challenges to this pattern through new alternate initiatives.
  - even the government initiatives subordinate themselves to big business interests (NMITLI)
  - DPRP compelled to start neglected diseases programme
  - OSDD programme initiated
  - MSF induced PPPs

Challenges facing IP policy formulation: the case of India

- Contradictory actions being pursued in respect of application and management of intellectual property;
    - Introduction of Indian Version of Bayh-Dole Act;
    - Strong IPR jurisprudence used in the development of manual for patent examination
- New issues arising w. r. t IP; domestic industry response on (data exclusivity, TRIPS plus FTAs , compulsory licensing, patenting of research tools). IPA/IDMA demanding rejection of data exclusivity & defending Section 3 (d).
- Compulsions of changing innovation model ignored, Mashelkar Committee dithers on the issue of restricting product patents to NCEs/NMEs; unable to provide criteria for balanced patentability norms in respect of pharmaceutical substance & microorganisms.
- Global pharma is still arguing for stronger IPRs

IP Management Policy

- Issues in IP Management
  - IP capital management competence in industry & research organizations
    - Patent landscaping competence is still not organized.
    - Management of IP on genomics and research tools in the case of vaccines
    - No tracking of IP purchase in research agencies (No inventories available on IP purchases.
  - Patent manual fails, jurisprudence and IP awareness & training of all communities in respects particularly actions on
    - exclusions of discoveries, ESTs, gene sequences and higher life forms; Increase the costs of patent maintenance by redesigning patent renewal provision; Charge for each claim; discourage multiple claims; Discourage early filing, Disallow broad patents; No-reach through licenses; Use compulsory licensing as if license of right exists

Current Drug Development Paradigm and India's options

- For-profit Companies are the main driver; financial compulsions / greed trump health compulsions; 10/90 problem, 1% of new drugs for tropical diseases; 1980-2000, out of 1000 drugs only 1 quarter were better than what already existed in the market.
- Blockbuster model / incremental drug innovations/ product differentiation, Post-TRIPS-little improvement
- Out licensing (due to limited access to markets for domestic firms); supply side actions in the form of PPPs, & open source drug discovery as the emerging options, much to be done in respect of demand for improved essential medicines

R&D and innovation gap: Towards an assessment of challenge and progress w. r. t neglected diseases

- Failure to develop products for neglected diseases including insufficient health system research is a system failure; markets, disciplines, governments and institutions-share the blame.
- Now member states formally accept this consensus; WHA Resolution on public health, innovation & intellectual property reflects partially this development; conflicts & varying thrust persist.
- Progress made over the period of last one year is inadequate and would need concrete recommendations from WHA.

Indian involvement in PPPs

- Munos studied in 2006 a sample of 20PPPs, 72 ongoing projects for malaria, TB, AIDS, Kalazar and Diarrhoeal diseases, but even this new business model is only a small fraction
- Only 1 Ranbaxy company involved from India
- Gyatri Sabherwal's survey showed 8 cos invovement from India; Gland Pharma, GVK Bio, Odyessey (US entity), Advinus Therapetuics, Bharat Biotech, Serum Institute, Stride, Shantha Biotech

Challenge of Reward System

- Separate R&D costs from manufacturing costs, delink pricing from R&D costs, shift away needed from monopoly to open access
- Government patronage, prize funds, drug R&D taxes,
- Alignment of innovation, incentive and access
- Open source drug discovery, Track II patents rewarding medical needs

Pattern of competence in industry

- Weak drug discovery competence; industry has been competent to develop processes for off-patent drugs or analogues
- Drug Development; preclinical, animal work, working largely for foreign clients, mouse and rat facilities, not too many FDA stringent requirements meeting GLP facilities, facilities undertaking higher animal work absent.
- Clinical trials; study design, ethics approval , clinical operations, lab analysis, data mgm, biostatistics, pharmacovigilance, medical writing, regulatory filing.
- Clinical trials is a booming business in India, 700 clinical trial sites, confirmatory trials dominating, human volunteers, IT work

Gaps & mismatches

- Action initiated for pharmaceutical research in 2000, NCMH in 2005 too built a strong case; 11th FYP Working Group identified weaknesses and recommended for
  - Policy and plan and system development, attach higher priority to health system research, initiate a culture of research in medical colleges, promote good governance, infrastructure and regulatory capacity development, enhance allocations, facilitate translational research
- Assessment shows R&D mismatches; research not embedded in public health perspective; of the 4876 health research papers published in 2002 from India in Pub Med 48.4% BR, 47.4% clinical and 4.4% in Public health sciences (ASCI)

Research not embedded in public health perspective: ASCI Study

- 4876 health research papers published in 2002 from India in Pub Med 48.4% BR, 47.4% clinical and 4.4% in Public health sciences (ASCI). Of the 4495 papers based on original research, only 3.3% were in public health. Quality adjusted original research output (QAORO) was highest for non-communicable diseases (62% of total).
- Of the total QAORO the proportions in injuries (0.7%), cardio (3.6%), respiratory infections (0.2%), diarrhoeal diseases (1.9%), perinatal conditions (0.4%), childhood cluster diseases (0.5%) unipolar major depression (0%), and HIV/AIDS (1.5%) were substantially lower than their proportional contribution to the disease burden in India.
- The Australia-India ratio for QA health research output per unit gross domestic product was 20 and for public health research output was 31

Building of capacity for innovation

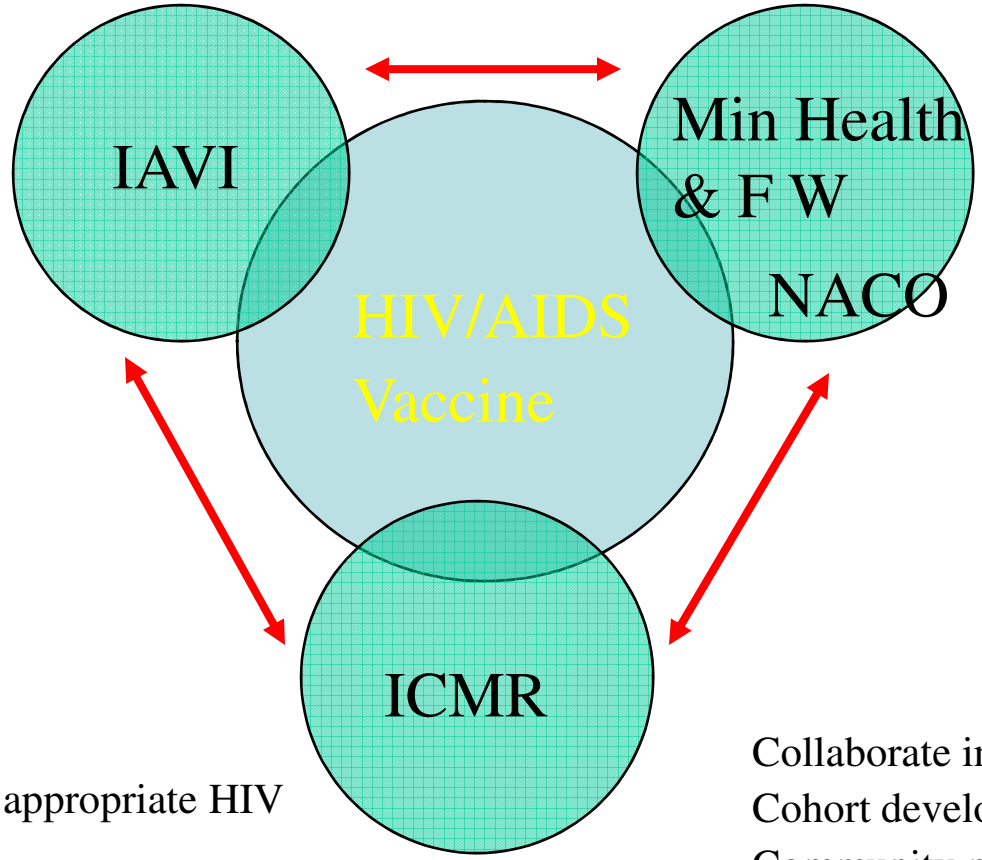
- Structure of manpower for health R&D; 700-?; pharmaceutical R&D in business sector; changing dynamics of business sector pharmaceutical R&D
- Fragmentation of R&D
- R&D is only one element; translational research gap; technology utilization ability gap; & lack of bridging organizations.
- Demand articulation
- Regulatory system

Role of Partners in HIV Vaccine Development

Design, develop and evaluate candidate vaccines appropriate for India

Capacity building, advocacy, training for vaccine trials

Transfer of technology for manufacture of vaccine in India



Facilitate permissions and permits

Harmonization of goals

Selection of Indian manufacturer

Select appropriate HIV strain

Provide technical expertise

Collaborate in pre-clinical trials

Cohort development

Community preparedness

Conduct clinical trials

Govt. initiatives for R&D –Drugs and Vaccines

NIMTLI

–Provides support to industry in areas where technology,product or market is certain

TDB

–Development and commercial application of indigenous technology, or adapting imported technology to widen domestic applications

PRDSF

–Promote industry-institutional R&D collaborations in drugs and pharmaceutical sectors to develop new drugs and vaccines, develop infrastructure

SBIRI

– Initiative launched by DBT to boost Public-Private partnership in biotechnology industry.

–**National Drug Regulatory Authority**

Setting up of National Drug Regulatory Authority

IND Molecules recommended for phase I clinical trial for various indications

- ✓ Anti-microbial agent(Ranbaxy)
- ✓ Nasal formulation FOR MIGRANE (Lupin)
- ✓ Anti-hyperglycaemic agent (CDRI)
- ✓ For treatment of Benign prostatic hyperplasia (Ranbaxy)
- ✓ Antibacterial agent (Wockardt)
- ✓ Anticancer agent (Reddy's and Nicholas Piramal)
- ✓ Adjuvant in the radiotherapy of cerebral glioma patients(DRDO)
- ✓ For treatment of overactive bladder and urinary incontinence (Ranbaxy)
- ✓ Herbal preparation for Psoriasis(Lupin)
- ✓ Antihistanic agent (Sun Pharma)
- ✓ Anti-tuberculosis(Lupin)
- ✓ For treatment of thrombolysis(Malladi)
- ✓ Dyslipidemias (Reddy's, Zydus)

Prioritization of R&D

- Lacking in disease wise mapping of priorities, gap analysis, formulation of prioritized strategies; effort made in the area of diarrheal diseases, weak in health system research
- A new department created in the ministry for health research; DGICMR given secretary status
- Health research policy draft enunciated, yet to be adopted
- Status of estimation of burden of disease (NCMH)

Actions required to be taken in respect of promotion of R&D

- Preliminary health research system analysis shows gaps & mismatches, narrow research base, fragmentation, lack of coherence, development gap, competence in biology growing, etc.
- National health research (policy, plan & system development)
- Need for performance based monitoring
- National health management research forum
- Concerns to be taken care of in the promotion of R&D- priorities of free projects, stability of funding, network development, access related IP management issues

Technology Transfer

- Research efforts undertaken in the area of diagnostics never translated into products due to change in tech import policy; even though priority was given to anti-infectives
- More recently among the govt signed 21 agreements; vaccine development for infectious diseases.
- CL mechanism is yet to be utilized; one application by Natco under 31 (f)

Status of mandated actions in India: An assessment

- Failure of TRIPS in stimulating R&D and innovation for neglected diseases is also a feature of national system of innovation in India.
- Although ahead of others in the roadmap making, but preparation is inadequate; lack of preparedness has its basis
  - poor state of awareness of mandated actions
  - prevailing myths & beliefs
- Widely prevailing confusion w. r. t the role of intellectual property in the generation and diffusion of health innovation
- Understanding prevailing regarding the role of health research in access and delivery

Concluding Remarks

- Challenge ahead
- Policy instruments for promotion & regulation of R&D & innovation for neglected diseases
- HRSA
- Legislative actions
- Intellectual Property Management
- Public in PPPs
- Financing & Collaborative Modes

Exercise

- Desirability & feasibility of shift in intellectual property (IP) regime for the benefit of public health
  - Changes in the nature of innovation model
  - Conflicts arising out of the emerging rationale of models of IP and changing innovation models
  - Analysis of moments of power and feasibility of alternative incentives
  - Some examples

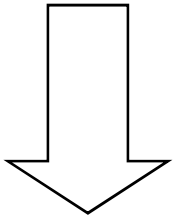
Test data protection:

TRIPS requirements & TRIPS-plus provisions

Karin Timmermans

Medicines are subject to two sets of rules:

Intellectual property rights



The right to exclude

But not the right to market or to use

Medicines are subject to two sets of rules:

Intellectual property rights

The right to exclude

But not the right to market or to use

Registration requirements

Authorization to put a medicine on the market

Reasons for regulating medicines:

- Market failure, especially information imbalance between manufacturers, prescribers and consumers;
- Ineffective or dangerous medicines may undermine confidence in the entire health care system;
- Money spent on ineffective or dangerous medicines is wasted;
- Misuse of certain medicines (such as antibiotics) can have serious implications for the individual and for public health.

Registration criteria:

Quality – Safety – Efficacy

Registration criteria:

Quality – Safety – Efficacy

preclinical and clinical trials (original)

Registration criteria:

Quality – Safety – Efficacy

preclinical and clinical trials (original)

or

chemical / biological equivalence (generics)

Data exclusivity:

During the data exclusivity period,

Authorities may not use or rely on those data to register generic equivalents.

As long as data exclusivity lasts:

Generic manufacturers will have to submit their own data to prove safety and efficacy

=> They will have to repeat the clinical trials and other tests

Alternatively, they can only enter the market after expiry of the data exclusivity period

NCE, "standard" situation:

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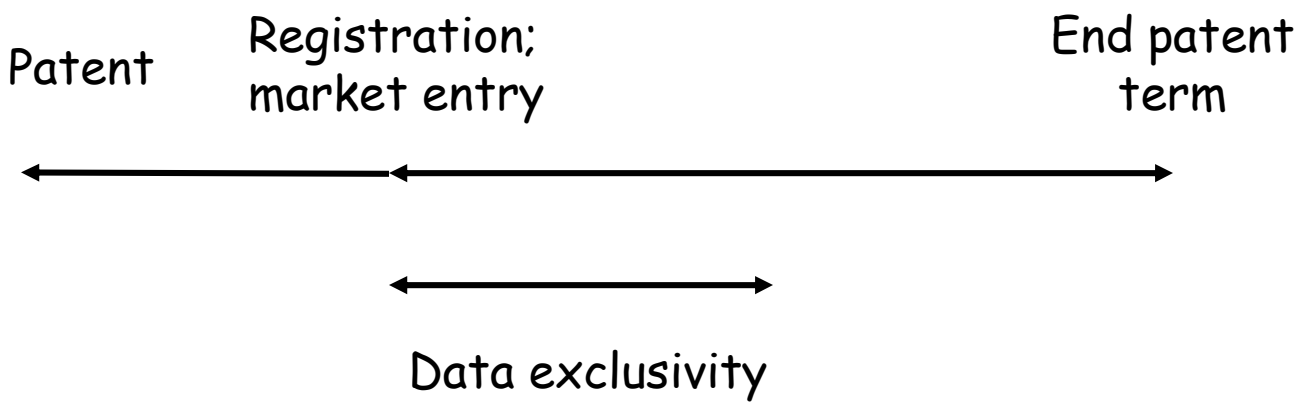
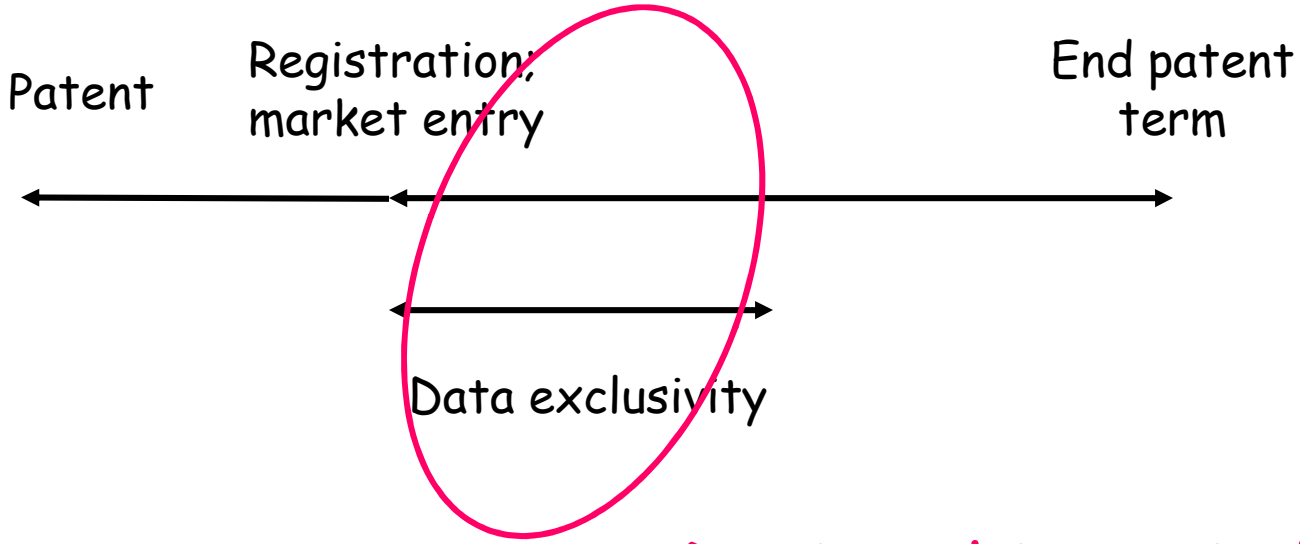


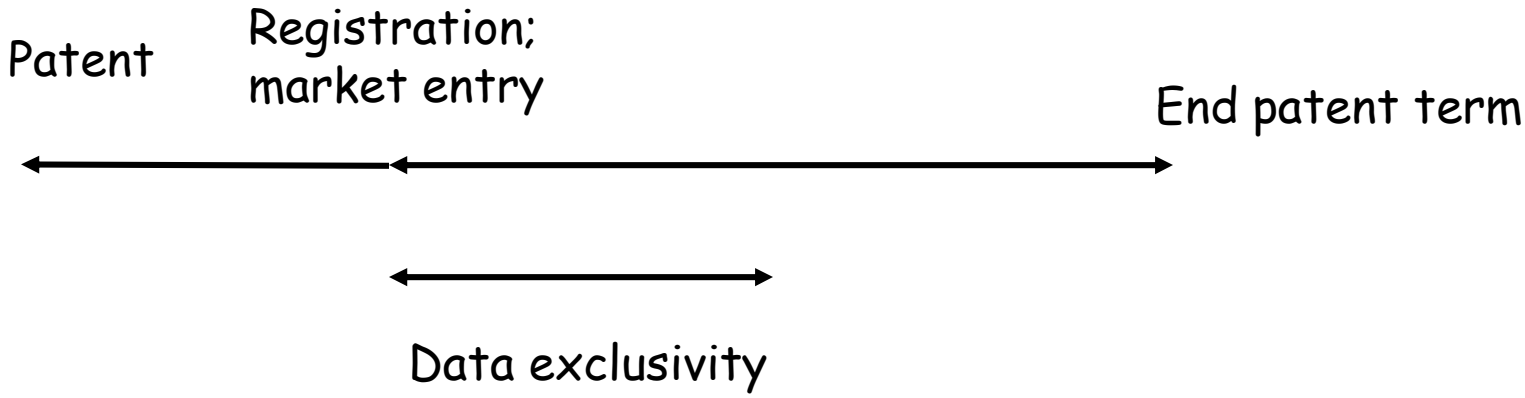
1. NCE, compulsory licensing:



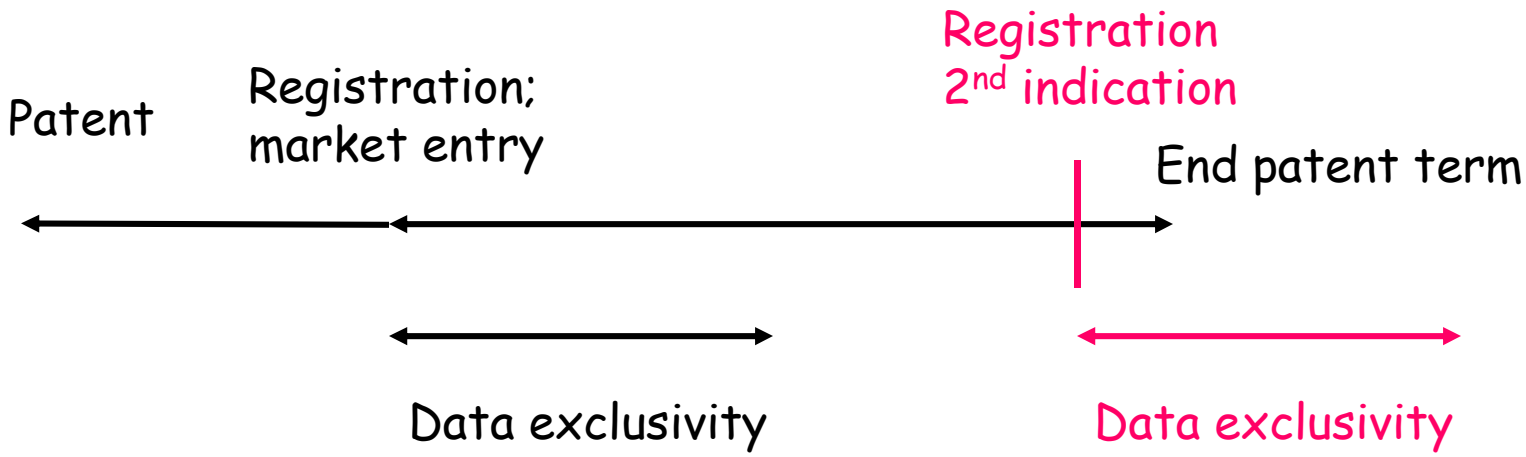
?

During this period, generics may not be able to enter the market, even when a CL has been issued

2. Second indication:



2. Second indication:



3. When there is no patent:

- When the drug is not new
- No patent law, or patents not granted for pharmaceuticals
- When the innovator did not apply for a patent

TRIPS Article 39.3

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Undisclosed data about
new chemical entities

should be protected:

- against disclosure
- against unfair commercial use

- Publication of undisclosed data is not allowed, except when necessary to protect the public.

- Authorities are not to share these data (for instance with generic companies).

“Unfair commercial use”

Does the Drug Regulatory Authority (DRA) actually use the data??

- Often not; the DRA may not even have the data;
- Even if the DRA does use the data, it is not commercial use.

Data exclusivity creates additional barriers to access to medicines.

TRIPS Article 39.3 does NOT require data exclusivity,

and national laws do not need to provide data exclusivity.

Data exclusivity in selected US FTAs

	Vietnam							
Exclusivity	**V**							

Data exclusivity in selected US FTAs

	Vietnam							
Exclusivity	**V**							
New indications	(v)							

Data exclusivity in selected US FTAs

	Vietnam	Laos						
Exclusivity	**V**	**V**						
New indications	(v)	(v)						

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile					
Exclusivity	**V**	**V**	**V**					
New indications	(v)	(v)						

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore				
Exclusivity	**V**	**V**	**V**	**V**				
New indications	(v)	(v)		(v)				

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore				
Exclusivity	**V**	**V**	**V**	**V**				
New indications	(v)	(v)		(v)				
Incl. foreign registration				**V**				

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore				
Exclusivity	**V**	**V**	**V**	**V**				
New indications	(v)	(v)		(v)				
Incl. foreign registration				**V**				
Incl. disclosed data				**V**				

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore				
Exclusivity	V	V	V	V				
New indications	(v)	(v)		(v)				
Incl. foreign registration				V				
Incl. disclosed data				V				
Can surpass patent term				V				

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore	Australia			
Exclusivity	V	V	V	V	V			
New indications	(v)	(v)		(v)	V			
Incl. foreign registration				V	V			
Incl. disclosed data				V				
Can surpass patent term				V	V			
"local" definition NCE					V			

Data exclusivity in selected US FTAs

	Vietnam	Laos	Chile	Singapore	Australia	Morocco	CAFTA	Bahrein
Exclusivity	V	V	V	V	V	V	V	V
New indications	(v)	(v)		(v)	V	V		V
Incl. foreign registration				V	V	V	V	V
Incl. disclosed data				V		V	(v)	V
Can surpass patent term				V	V			V
"local" definition NCE					V	V	V	V
"waiting period"							V	

Trade, patents and access to medicines

Background and current issues

Karin Timmermans
WHO

Centad-IIFT School on Trade and Public Health, 5 October 2009, New Delhi

Outline

- Background
  - Safeguards and their use
  - Other (upstream) flexibilities
- Recent developments

TRIPS Agreement:

- **Agreement on Trade-Related Aspects of Intellectual Property Rights**
- **is an integral part of the WTO Agreements**

WTO Agreements:

- **binding on all WTO Member States**
- **subject to WTO's dispute settlement mechanism**

Patents are a public policy tool:

- **to reward and promote innovation**
- **to disclose the invention in order to make it available**

A patent provides a time-limited monopoly right over an invention

TRIPS requirements for patents:

- all fields of technology
- product and process inventions
- minimum standards: 20 years
- effective enforcement

TRIPS has harmonized standards for patents.

For most developing countries, these new standards are higher than their previous standards.

TRIPS delays the introduction of generics (and generic competition)

=> It will take longer before prices of new medicines come down

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For most developing countries, these new standards are higher than their previous standards.

TRIPS delays the introduction of generics (and generic competition)

=> It will take longer before prices of new medicines come down

Proponents expect TRIPS will:

- **enhance local innovation**
- **increase foreign direct investment**
- **increase technology transfer**

Limited evidence that this will happen

Study Thailand:

(introduced pharmaceutical patents in 1992)

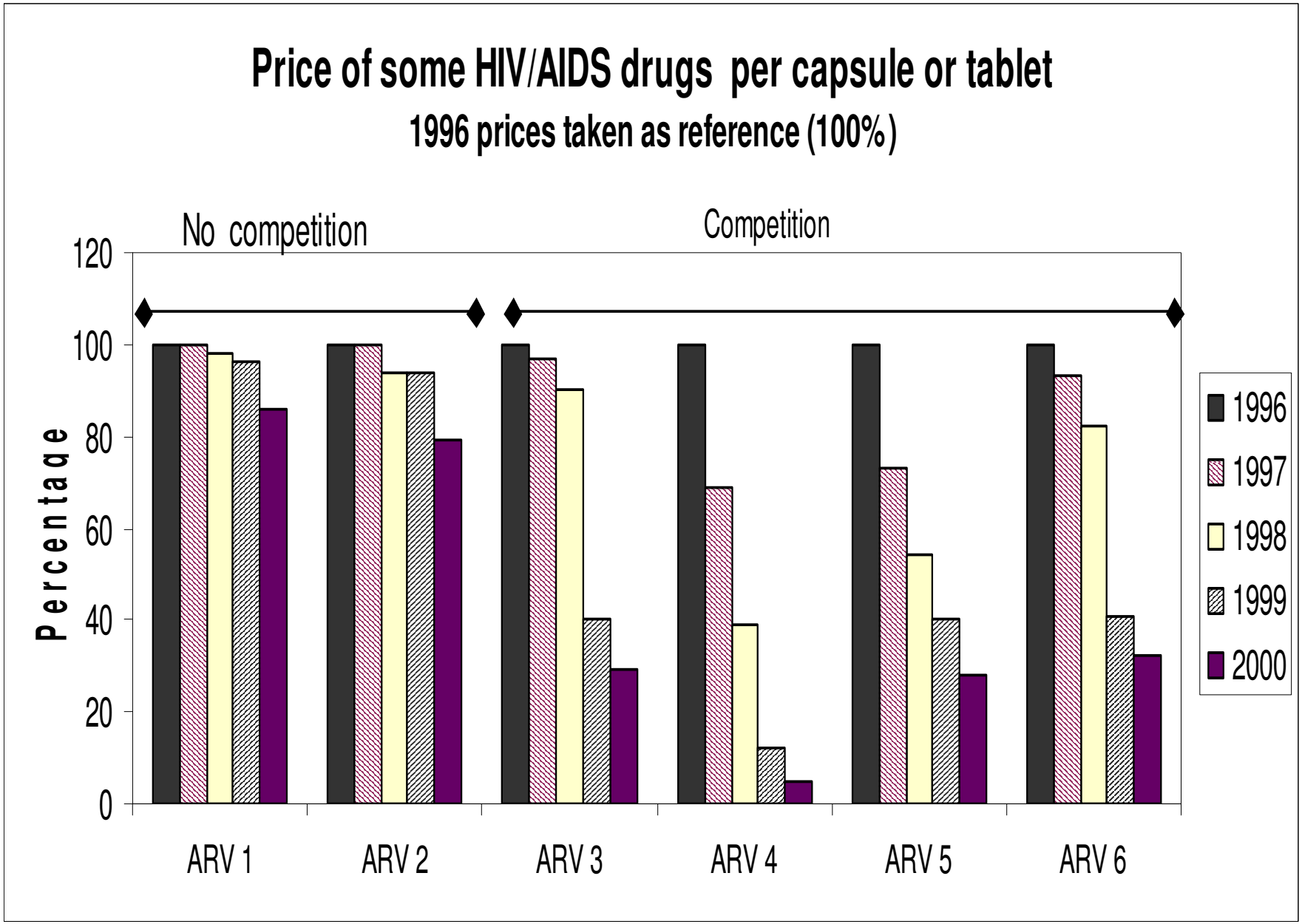
- **technology transfer minimal**
- **imports increased**
- **little foreign direct investment**

Broad agreement:

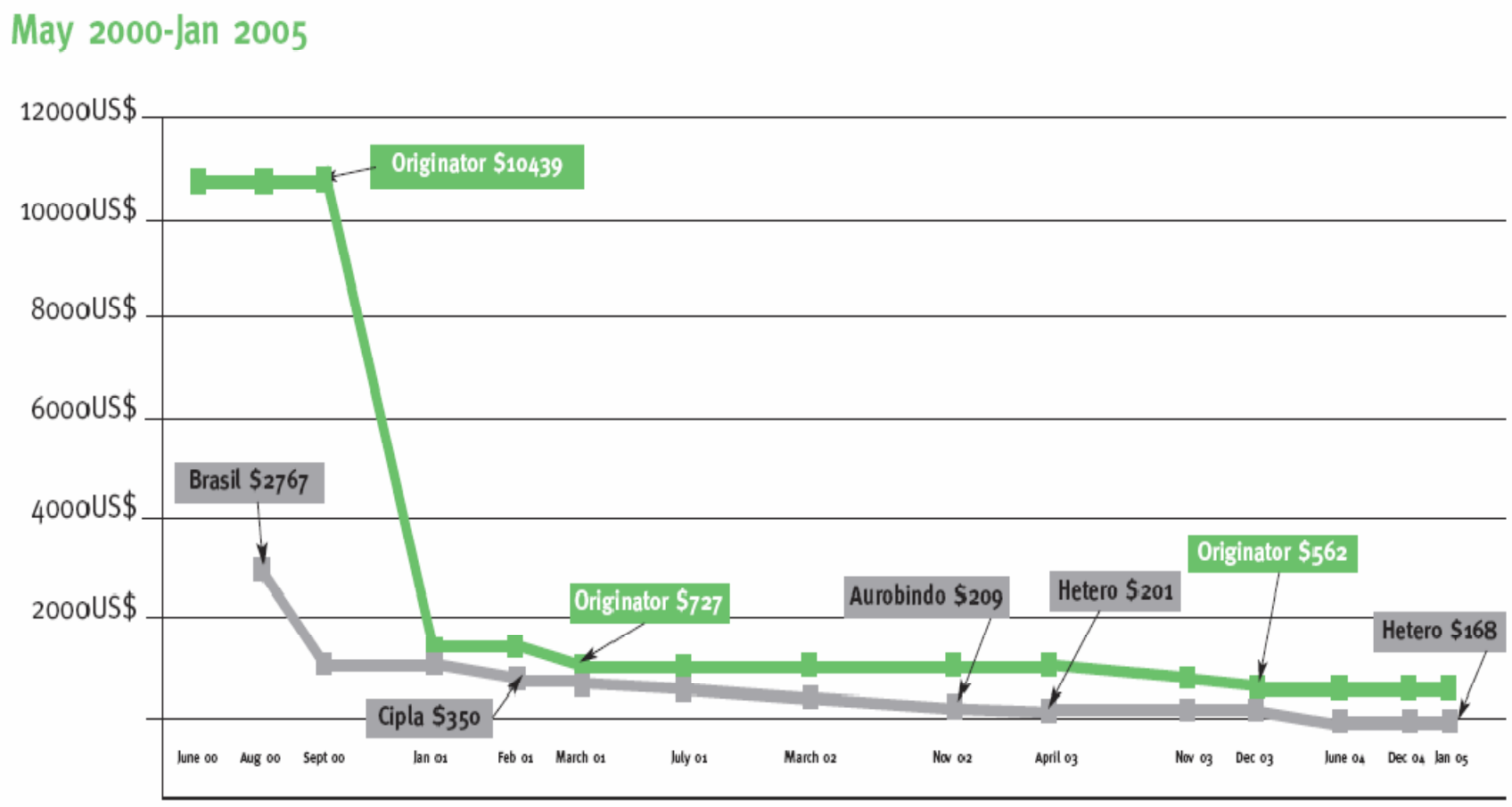
Introduction of TRIPS standards will delay the introduction of generic versions of ***new*** drugs

$\Rightarrow$ It delays competition and price reductions

$\Rightarrow$ **Prices of new drugs will remain high for a longer time**


Price of some HIV/AIDS drugs per capsule or tablet
1996 prices taken as reference (100%)
No competition
Competition
120
100
80
60
40
20
0
Percentage
ARV 1
ARV 2
ARV 3
ARV 4
ARV 5
ARV 6
1996
1997
1998
1999
2000

Prices of 1st line anti-retrovirals



Sample of ARV tiple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year. Generic competition has shown to be the most effective means of lowering drug prices. During the last four years, originator companies have often responded to generic competition.

Source: MSF, 2005

TRIPS contains safeguards that can protect access to medicines:

- Parallel importation
- Compulsory licensing, including:
  - for export to countries without domestic manufacturing capacity
  - for government use
- 'bolar' provision

These safeguards can only be used when incorporated in the national legislation

“Bolar” provision

- allows testing and regulatory approval of generic drugs before patent expires

- accelerates the onset of generic competition after the patent expires

Parallel importation

- importation without the consent of the patent holder, of a patented product marketed in another country, either by the patent holder or his licensee

- allows “shopping around” in the international market for the best price (of the patented product)

Compulsory license (CL)

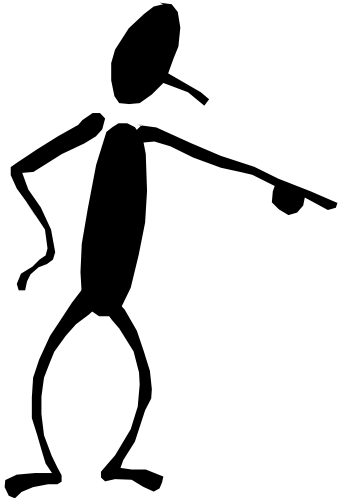
- license granted without patent holder's permission;
- introduces generic competition ***before*** the end of the patent term;
- many countries' laws have CL provisions;
- TRIPS allows CL in case of national emergency or extreme urgency, public non-commercial use, or to remedy anti-competitive practices etc.;
- TRIPS does ***not*** limit the grounds (reasons) for CL, but imposes ***conditions*** on a CL;
- a compulsory license can be issued for local production or for importation.

TRIPS leaves countries free to determine the grounds for compulsory licensing, but specifies ***conditions*** to be applied to Compulsory Licensing, including:

- case-by-case decision
- first: try voluntary license
- adequate remuneration of patent holder
- non-exclusive, non-assignable
- predominantly for domestic market

However, TRIPS limits the capacity ***to export*** medicines produced under a compulsory license.

The Doha Declaration on TRIPS and Public Health



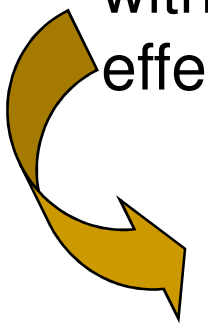
Confirms:

TRIPS can and should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health, particularly access to medicines.

The Doha Declaration...

Furthermore says that:

- Countries have the right to use compulsory licensing and parallel importation to ensure access to medicines;
- Countries are free to determine the grounds for issuing a compulsory license;
- LDCs don't have to implement patents and data protection for pharmaceuticals until 2016;
- Recognizes (in paragr. 6) that it is not clear how countries with insufficient or no manufacturing capacity can make effective use of compulsory licensing.



A solution for this was agreed (in August 2003) but has only been used once.

Key elements of the solution:

- countries should first notify WTO (except least-developed countries);
- provide details of drugs to WTO;
- possibly 2 compulsory licenses (importing *and* exporting country);
- special labeling, packaging and/or coloring/shaping;
- notify WTO of the grant of compulsory license;
- prevent re-exportation;
- annual WTO review of the system;
- some countries have opted out/only for emergency.

Government Use

A special case of compulsory license – i.e. a compulsory license for the Government itself.

- Procedures tend to be easier;
- Medicines produced under Government Use license cannot be sold commercially.

Compulsory licensing – the case of Thailand

- Thailand issued several compulsory licenses
  - Nov. 2006 (efavirenz)
  - Jan. 2007 (lopinavir/ritonavir and clopidogrel)
  - Jan. 2008 (imatinib, docetaxel, letrozole and erlotinib)
- Opponents say compulsory licensing is:

  i) only for communicable diseases, ii) only for emergencies, and iii) only after prior negotiations with patent holder.
- Points i) and ii) are wrong, while iii) is waived in certain cases, incl. public non-commercial use (government use).

Only a few compulsory licenses in developing countries

- Zimbabwe: for local production and/or import of all HIV and AIDS related drugs (April 2003)
- Mozambique: for local production of an FDC of lamivudine, stavudine and nevirapine (April 2004)
- Zambia: for local production of an FDC lamivudine, stavudine and nevirapine (Sept. 2004)
- Malaysia for importation of didanosine and zidovudine (Oct. 2003)
- Indonesia (mainly) for local production of lamivudine and nevirapine (Oct. 2004), and efavirenz (March 2007)
- Brazil for efavirenz (May 2007)

India - patentability standards

Patents Act of India – section 3(d):

The following shall not be treated as an invention :

“ 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.”

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Example: Levofloxacin – patenting of isomers

Patent No.: US 4,382,892
In force until: 2 September 2003

Protects ofloxacin.

Patent No.: US 5,053,407
In force until: 1 October 2008

Claims levofloxacin, the S-(-)- isomer of ofloxacin.

India – the Novartis saga

- CPAA used pre-grant opposition procedures to file an opposition against Novartis' patent application for imatinib mesylate (Gleevec/Glivec) in 2005
- Novartis price for imatinib: Rs 125,000 pp/pm; Indian generics price: Rs 12,000-8,000 pp/pm
- CPAA claimed imatinib mesylate merely "new form" (i.e., crystal salt form) of "known substance" (i.e., imatinib) without increased efficacy
- Indian Patent Office agreed, rejected patent
- Novartis appealed rejection, also challenged validity of section 3(d) of the Patents Act as inconsistent with TRIPS and the Indian Constitution

Recent developments

Recent developments (1): Innovation

- In recent years, it has become increasingly clear that insufficient R&D is taking place for diseases that disproportionately affect developing countries:
- Data show that of 1400 new drugs developed between 1975 and 1999, only 13 (1%) were for tropical diseases or “neglected diseases”.

Recent developments (1): Innovation

- In recent years, it has become increasingly clear that insufficient R&D is taking place for diseases that disproportionately affect developing countries:
- Data show that of 1400 new drugs developed between 1975 and 1999, only 13 (1%) were for tropical diseases or “neglected diseases”.

This realization has led to renewed attention, and increased R&D efforts, for the development of medicines for “neglected diseases”.

Recent developments (1): Innovation

- Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property (resolution WHA 61.21)
  - to promote new thinking on innovation and access to medicines;
  - to enhance needs-based research and development (R&D) relevant to diseases that mainly affect developing countries.

- GSPOA – very broad scope:
  1. Prioritizing research and development needs
  2. Promoting research and development
  3. Building and improving innovative capacity
  4. Transfer of technology
  5. Management of intellectual property
  6. Improving delivery and access
  7. Ensuring sustainable financing mechanisms
  8. Establishing monitoring and reporting systems

Recent developments (2): “TRIPS-plus”

“TRIPS-plus” refers to requirements to provide a higher level of protection than required by TRIPS.

Examples:

- Extension of the patent term beyond 20 years in certain cases;
- Limit the grounds for issuing compulsory licenses;
- **Data exclusivity** for pharmaceuticals: during the exclusivity period the Regulatory Authority (FDA) cannot rely on the originator’s data to register generic versions;
- “**Linkage**”: the Regulatory Authority should refrain from registering generic versions of drugs under patent.

TRIPS-plus provisions further constrain access to medicines

Recent developments (3): counterfeit

- Several international initiatives against counterfeiting, e.g. WHO (IMPACT) and WCO (SECURE). Some countries appear to be negotiating ACTA.
- A common feature reportedly is the focus on enforcement
- There are worries about blurring of concepts: counterfeit, substandard, generic
- Fears have been expressed that these initiatives may hamper trade in genuine generics: e.g. prequalified Indian ARVs procured by UNITAID for Nigeria were confiscated during transit in the Netherlands

Compulsory licensing for Access to Essential Medicines

Médecins Sans Frontières(MSF)

Campaign for Access to Essential Medicines

Since 1999 working internationally to improve access to essential medicines

7 October, 2009

Why are we concerned about patents?

Patent monopoly keeps prices high – essential drugs can be100 times more expensive

"Generic competition keeps prices low"

The situation pre-TRIPS:

- **India** Patents Act, 1970, no patents on pharmaceutical products (**Based on German model**)
- **India (generic co(s) produce APIs and formulations** (an important source of low cost, quality drugs for developing countries)

CAMPAIGN FOR
ACCESS
TO
ESSENTIAL
MEDICINES

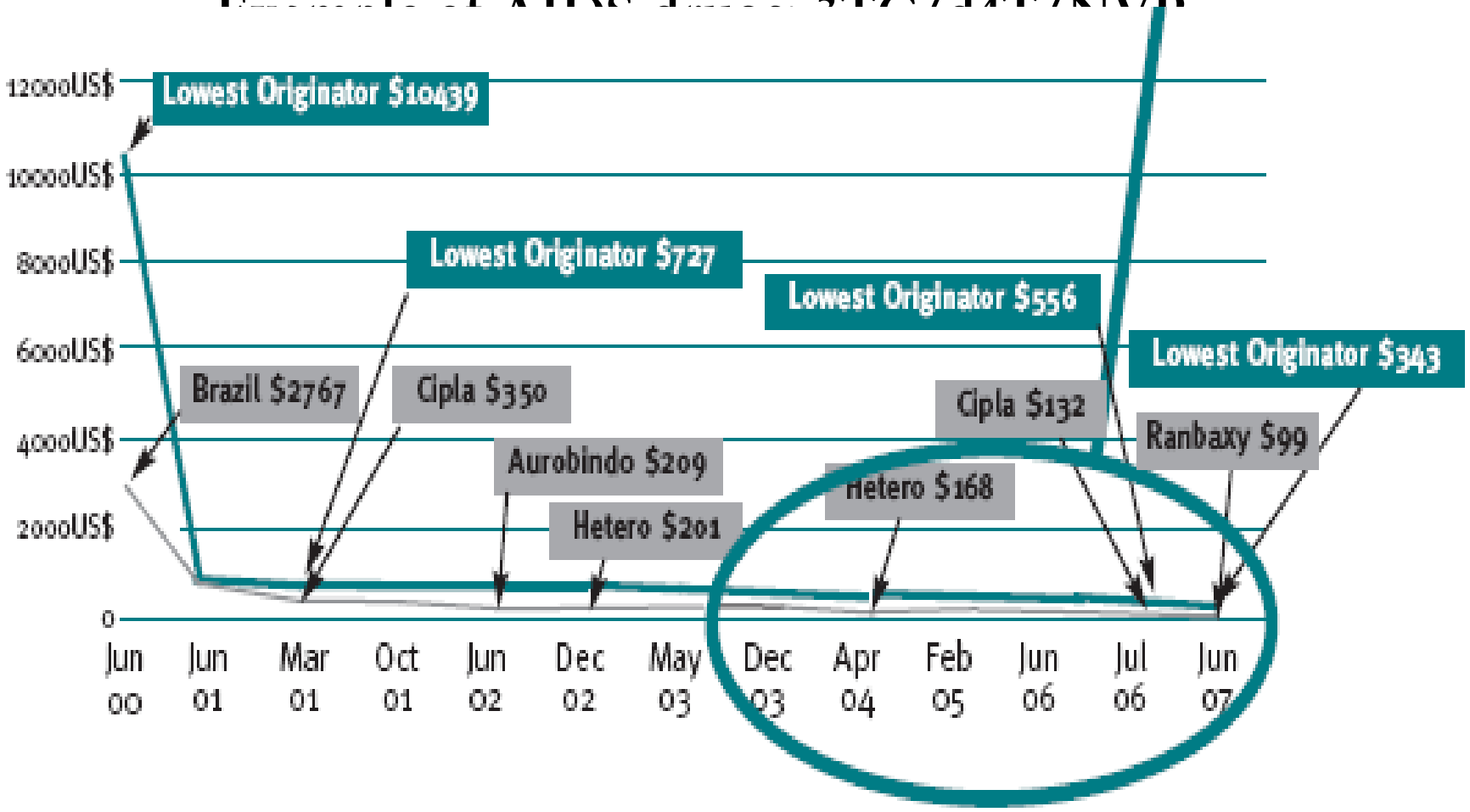
MEDECINS SANS FRONTIERES

Why are we concerned about patents?

- 100% of AIDS drugs used by GoI for HIV/AIDS treatment are affordable generic drugs
- 84% of the drugs used by MSF for treating more than 100,000 people living with HIV/AIDS in 30 different countries are affordable generic antiretrovirals

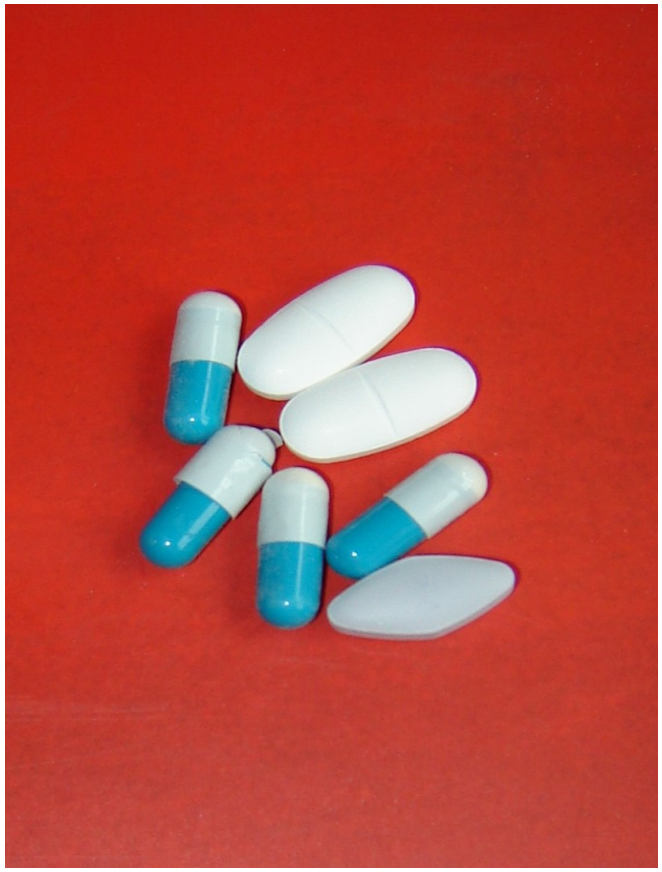
Production of /access to quality affordable generic medicines is therefore key in making life-extending treatment available to more people who need it.

Generic Competition needed to Drive Prices Down



Absence of patents leads to "three in one AIDS pill"
Eg. *d4T/3TC/NVP* (fixed dose combination – FDC)

- Individual compounds were not patented in India
- Made treatment simplified in resource poor countries



India a Key Supplier of life saving drugs

- 50% of PLWA in the developing world depend on Indian generics
- 67 % of medicines exports from India go to developing countries.
- Approx. 50% of the essential medicines that UNICEF distributes in developing countries come from India
- 75-80% of all medicines distributed by the International Dispensary Association (IDA) are manufactured in India.
- In Zimbabwe, 75% of tenders for medicines for all public sector health facilities from India
- Lesotho, buys nearly 95% of all ARVs from India

Globalisation of Patent Rules

- 1995 WTO Trade related aspects of intellectual property rights agreement (TRIPS)
- "minimum" standards of protection of intellectual property rights
- **20 year patents on pharmaceutical products**
- No differentiation between lifesaving medicines and trivial goods

...impacts on generic production

- **Indian co(s) can no longer produce a low cost essential drug if a patent is granted**

E.g. of drugs patented in India

- **HIV/AIDS –** valganciclovir, etravirine, raltegravir
- **Cancer –** erlotinib, sunitinib maleate, dasatinib
- **Hepatitis C -** pegylated interferon alfa-2a

However the role of Indian generics is crucial to getting life-saving drugs to patients. The patented version of Erlotinib, a treatment for lung cancer, sells for Rs. 4,800 a tablet. The generic costs Rs. 1600 a tablet – three times less

Need for Compulsory Licensing to reduce prices

Need:

- If patented drugs are unaffordable and/or unavailable. A compulsory license for local production is often the only solution to solve procurement problems, increase local availability of drugs and save on costs for patients and the national health budget.

Why:

- Increase the power of the Ministry of Health to purchase drugs and medicines from sources independent of the patentee
- Increase access to affordable medicines of patients in India and other developing countries

How:

- Compulsory Licensing allows generic competition. License to produce /sell to competitor to reduce prices

TRIPS agreement

- Enshrined in Article 31 of the WTO Agreement on TRIPS, a member country's law can authorize someone else to produce a patented drug without the consent of the patent holder in the event of a national emergency, extreme urgency or for non commercial public use. Compulsory licenses are a legally recognised means to overcome barriers in accessing affordable medicines.

Doha Declaration on TRIPS and Public Health

- **Provides guidance for the interpretation of the relevant parts of the Agreement**
- **First**, it emphasizes that the TRIPS Agreement does not and should not prevent WTO members governments from taking measures to protect public health. It reaffirms the members' rights to use fully the provisions of the TRIPS Agreement, which provide flexibility for this purpose.
- **Second**, the declaration makes it clear that the TRIPS Agreement should be interpreted and implemented in a manner that supports WTO members' right to protect public health and, in particular, to promote access to medicines for all.
- **Third,** each member has the right to grant compulsory licences and the freedom to determine the grounds for such a licencethe declaration makes it clear that each member is free to determine the grounds upon which the licences are granted.
- **Fourth,** extended the transition period for LDCs for implementation of the TRIPS obligations from 2006 to 2016.

Patents on essential drugs: Need for Compulsory Licensing

Thailand:

Thai Health authorities issues compulsory licenses in 2006/2007 on AIDS drugs (efavirenz & kaletra) & heart disease drug (Clopidogrel) for universal health scheme

> Reduced the price of Clopidogrel from 70 baht/day to
7 baht/day

> Threat of CL: Novartis agrees to supply the Thai govt imatinib (gleevec) free of cost

CL in other Asian countries

- March 2007, Indonesia reportedly issued compulsory license on AIDS drugs EFV, 3TC and NPV

- 2007, Malaysia issued compulsory license on ddI, AZT and Combivir-3TC+AZT, to import generic drugs from India)

In other developing countries……

- 25 April 2007, Brazil government issued a statement to identify EFV to be of "public interest"; 4 May 2007, Brazil government issued compulsory license on EFV

- From 2001, more than 9 African countries have issued compulsory license on ARVs, including South Africa, Ghana, Zambia and Cameroon

Compulsory license: India

Indian patent law

« Sec. 83 «

- offers a good framework for the use of compulsory licenses in the interest of public health;
- refers to Articles 7 and 8 of the TRIPS agreement and the Doha Declaration on Public Health.

compulsory licensing in the interest of public health
Indian Patent Act

Specific Provisions:

Sec. 84 – On application by generic companies

Sec. 92 – notification by central govt for public non-
commercial use/national emergency/extreme urgency

Sec. 92A – for export

Sec. 100 – govt use

No royalty guidelines

- CL provisions allow for generic manufacture of drugs even if they are now protected by Indian patents.

- However, there is an important outstanding issue - may impact the use of CLs for manufacture of drugs by generic manufacturers – no royalty guidelines/cap.

- To minimize the incidence of expensive and delaying litigation, several countries have provided for royalty caps.

- Canada, for instance, has capped royalty payments for export of medicines under compulsory licenses to countries that lack manufacturing capacity at a maximum of 4%

Sec. 84 – Important provision under which application by generic companies is allowed

Unnecessary provisions delaying and restricting CL in

cases of unavailability or excessive pricing of

medicines

Sec. 84 (1) – delay - 3 year waiting period that will have a severe detrimental impact on the lives and health of patients in India and in other developing countries

Sec. 84 (6) – further delay - mandates negotiations with patent holder

Sec. 87 – further delay - opposition by patent holder

Why is section 84 important

- Sec. 92 & 100 covers government procurement
- **However 70%** of Indians access healthcare from the private sector
- Therefore provisions allowing **generic manufacturers to apply for a CL** are equally important
- Section 84 will cover essential drugs not covered by any notification of the central government

Sec. 92 – notification by central govt for public non-commercial use/national emergency/extreme urgency

The Ministry of Health and Family Welfare has a crucial

role in notification

The MoH would have access to ready information:

- about the importance of particular drugs;
- the requirement by public health facilities (NACO, TB program etc);
- the impact of high prices on the health budget;
- the version of the drug most necessary for public health purposes

- **Sec. 92 (3) – waiver of Sec. 87 i.e. opposition by patent holder on the discretion of patent controller – should be mandatory**

Section 90.2 –barrier to importing raw material

- Sec 90 (2): forbids the grant of CL for purposes of importation, which may raise problems in cases importation of raw materials needed for the manufacture of essential medicines in India;
- Even though this restriction can be waived by order of the Central Government to the Controller [Sec.92(3)], such a process may delay the supply of affordable essential medicines to the public;

whereas the TRIPS Agreement does not impose any restrictions on importations under compulsory licenses

Price after negotiation unaffordable

Difficulties:

- Price of patented drug in other countries even after price negotiation is not affordable!

E.g. Lopinavir/Ritonavir heat stable:

- *In 2006 no Indian generic on the market*
- Prices obtained in **Brazil** after price negotiation $1518/ppy
- **In Thailand in two years of negotiations:**
- Before 2006 – 2967/ppy
- In 2006 – 2000/ppy
- Thais issue CL. Abbott offers $1000/ppy
- First generic comes on the market in 2007 >$676/ppy >$500
- Thais buy the generics
- **Brazil is still paying $1518/ppy to Abbott**
- Middle income countries are unable to pay high prices of MNCs

Price negotiations?

Efavirenz 600 mg

Used in the treatment

of HIV/AIDS, first line

& second line therapy,

prescribed by WHO

Merck is the originator company

- **Not patented in India**
- (under opposition on grounds of new form of old drug)
- More than four producers. Lowest price **$ 165/ppy**

Patented -

- Thailand $468/ppy
- Brazil - $580/ppy
- China - **$ 900/ppy** (Merck)

Price negotiations

> generic reference pricing crucial!

EFV price negotiation in Brazil

- In 2003 for EFV - Merck offers Thailand $760/ppy
- Since 2004 Merck prices EFV in Thailand $468 /ppy
- In 2006 Thailand issues CL > $216 > $170 /ppy
- Merck after CL offers Thailand $288 /ppy

EFV price negotiation in Brazil

- In 2006 Brazil pays $580 /ppy (price after price negotiations
- After price negotiation Merck offers Brazil 2%discount on $580 > $568 /ppy
- Brazil issues CL > $170 /ppy

Thai Ministry of Public Health

"Prior negotiation with the patent holders is not an effective measure and only delays the improvement of access to essential medicines. It is only after the threat or the decision to use and implement Compulsory Licensing or Government Use of Patent that the negotiation will be more successful and effective."

Those who advocate for prior negotiation should realize these facts.

"The attempt to push for prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations."

Pg 6, Facts & Evidence Related to Govt Use of Patents in Thailand

UK Crown Use of Medicines Patents for Supply of Generics to the NHS

- *"Although this power of the Ministry of Health to purchase drugs and medicines from sources independent of the patentee has been much criticised by the pharmaceutical industry, it is not likely to be affected by such criticism. Such power will be exercised if the patentee is alleged to maintain unduly high prices for these products (Stephen Ladas,1975)."*

A paradigm shift is needed:

Changing patent rules to prioritize people's health needs over profit

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Public Health and Intellectual Property Rights: TRIPS Flexibilities

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Cochin, Kerala, India

nsg

Introduction

- Background of TRIPS
- Subject matter of protection
- Compulsory Licence
- Exceptions
- Parallel import
- Options for India

nsg

Background of TRIPS

- Flexibilities under Paris Convention and protection of public health
- No definition for Inventions
  - Possibility to exclude certain inventions
  - Product or process patent
- Freedom on nature of rights and term of protection
  - Exclusion of right of importation
  - Different term of protection

nsg

Background of TRIPS

- Freedom to issue compulsory licence
- No enforcement mechanism
- Freedom to structure patent law to protect domestic concerns like public health and food security
  - No product patent for medicine
  - Compulsory and statutory licence to prevent abuse of patent monopoly

nsg

International Concerns

- Growth of generic industries in many countries including in India
  - Drugs at affordable cost in developing economies
- Export of cheap generics to developed countries from developing countries
- Loss of income to Pharma industries in developed countries – distortion of trade?
- Demand to include TRIPS in WTO

nsg

Objectives of TRIPS

- Recognize IP as private right
  - Setting new standards for IPR protection
  - Strengthen the rights of owners of IPR
  - Facilitate enforcement of rights
  - Mechanism for settlement of Dispute
- Promotion of technological innovation and facilitate transfer of technology
  - Ensure social and economic welfare
  - Balancing of rights and obligation

nsg

Objectives of TRIPS

- Protection of public health and nutrition
  - Promote public interest in sectors of vital importance to socio-economic and technological development
  - Such measures are consistent with the provisions of TRIPS
- Balancing of public and private interest
  - Continued economic growth of developed countries and protecting the basic needs of poor in the developing countries

nsg

Patent under TRIPS

- Subject matter of patent protection
  - Any invention in all fields of technology
  - Invention may be a product or process
  - Invention must be *new*, involve *inventive step* and *capable of industrial application*
  - No discrimination based on field of technology and whether products are imported or locally produced
- Takes away the freedom of countries to ***totally*** exclude patent protection for inventions in sectors of public health, nutrition and socio-economic development

nsg

Pharmaceuticals

- Patent protection for pharmaceuticals and agricultural chemicals
- Patent protection for life form
  - Patent for microorganism
  - Patent for non-biological and microbiological processes for the production of plants or animals
  - Patent or *sui generis* protection for new plant varieties
- Patents for bio drugs

nsg

Pharmaceuticals

- Limited freedom enjoyed by the member states to protect public health
  - Standards of patentability left open
    - No definition for inventive step
  - Freedom to set higher standards to prevent ever greening of patent monopoly
    - New use of known substance
    - Patent for marginal improvements like dosage form, change of salt and ester etc. to improve effectiveness
  - This may facilitate access to improved drugs and promote growth of generic industries

nsg

Compulsory Licence

- Limited to individual inventions
- Need for prior consultation and failure to obtain licence with in reasonable time and terms
- Prior consultation is waived
  - In case of a national emergency
  - Other circumstance of extreme urgency
  - In case of public non-commercial use
- Nature of the market - predominantly for the supply of domestic market
- Payment of reasonable royalty

nsg

Compulsory Licence: Doha

- Implementation of TRIPS obligation supportive of public health and promote access to medicine to all
  - Freedom to determine the grounds of licence
  - public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and ***other epidemics***, can represent a national emergency or other circumstances of extreme urgency
  - Freedom to interpret exhaustion of rights – parallel import

nsg

Compulsory Licence: Doha

- Find solution to access to medicine to countries with no manufacturing capability
  - Allow countries to issue compulsory licence exclusively for exporting patented drugs to countries with no manufacturing capacity
- This gives limited flexibilities to structure domestic compulsory licence provisions to reduce the abuse of patent monopoly and facilitate access to essential drugs

nsg

Rights and Exceptions

- Right to make, use, sell and import patented products and process
- Scope of importation right
  - Right to regulate the movement of patented goods from one country to another
  - Gives the scope for differential pricing – different prices for the same goods based on purchasing power

nsg

Exceptions

- Freedom for providing limited exceptions to the exclusive rights
  - 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.

nsg

Exceptions

- Research and educational exceptions
- Exceptions to bring the products into the market as soon as the patent term is over
  - Bolar Exceptions
    - Freedom to use the patented invention to generate data necessary for approval by the regulatory authorities
  - Manufacturing and stocking
    - WTO panel in Canadian case refuse to recognize this since it may lead to abuse

nsg

Exhaustion of rights

- Exhaustion of rights
  - First sale doctrine
    - Freedom of the goods to move without restrictions once the goods are legally manufactured and sold in the market
- International, regional and national exhaustion
  - International exhaustion give freedom of goods to move all over the world market once it is legally manufactured and sold in one country

nsg

Parallel Import

- Facilitate the import of patented goods from markets where the price is low
- Regulate the price of goods through market mechanism
  - The owner of patent forced to fix the price so as to make third party importation less attractive
- Improve access to goods at affordable cost
- Conflict with the importation right – limitation of territorial licencing of patent rights

nsg

Parallel Import

- Countries dependent on foreign patented goods prefer to include provisions for parallel import
  - The economic benefit of low pricing of products and saving of foreign exchange
- Countries with strong domestic IP and industrial activity prefer to prohibit parallel import
  - Protect the interest of the domestic manufacturer
  - Market takes care of the interest of the consumer ?

nsg

Parallel Import

- Article 6 of TRIPS
  - For the purposes of dispute settlement
  - Nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.
- Freedom to determine exhaustion of right and facilitate parallel import
  - Developing and least developed countries benefit by providing express provision to encourage parallel importation

nsg

Options for India

- Public health
  - Limit the scope of patent protection – so more drugs will be out of patent protection and generics could be manufactured
  - Introduce liberal exceptions
  - Use the compulsory licencing provisions effectively so that the patented drugs are available at affordable cost
  - Facilitate parallel import to regulate prices
  - Facilitate export of patented drugs to countries with no manufacturing capability and promote industrial growth

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Public Health and Intellectual Property Rights: TRIPS Flexibilities

Prof. N.S. Gopalakrishnan
Centre for IPR Studies,
Cochin University of Science and Technology,
Cochin, Kerala, India

nsg

Introduction

- Background of TRIPS
- Subject matter of protection
- Compulsory Licence
- Exceptions
- Parallel import
- Options for India

nsg

Background of TRIPS

- Flexibilities under Paris Convention and protection of public health
- No definition for Inventions
  - Possibility to exclude certain inventions
  - Product or process patent
- Freedom on nature of rights and term of protection
  - Exclusion of right of importation
  - Different term of protection

nsg

Background of TRIPS

- Freedom to issue compulsory licence
- No enforcement mechanism
- Freedom to structure patent law to protect domestic concerns like public health and food security
  - No product patent for medicine
  - Compulsory and statutory licence to prevent abuse of patent monopoly

nsg

International Concerns

- Growth of generic industries in many countries including in India
  - Drugs at affordable cost in developing economies
- Export of cheap generics to developed countries from developing countries
- Loss of income to Pharma industries in developed countries – distortion of trade?
- Demand to include TRIPS in WTO

nsg

Objectives of TRIPS

- Recognize IP as private right
  - Setting new standards for IPR protection
  - Strengthen the rights of owners of IPR
  - Facilitate enforcement of rights
  - Mechanism for settlement of Dispute
- Promotion of technological innovation and facilitate transfer of technology
  - Ensure social and economic welfare
  - Balancing of rights and obligation

nsg

Objectives of TRIPS

- Protection of public health and nutrition
  - Promote public interest in sectors of vital importance to socio-economic and technological development
  - Such measures are consistent with the provisions of TRIPS
- Balancing of public and private interest
  - Continued economic growth of developed countries and protecting the basic needs of poor in the developing countries

nsg

Patent under TRIPS

- Subject matter of patent protection
  - Any invention in all fields of technology
  - Invention may be a product or process
  - Invention must be *new*, involve *inventive step* and *capable of industrial application*
  - No discrimination based on field of technology and whether products are imported or locally produced
- Takes away the freedom of countries to ***totally*** exclude patent protection for inventions in sectors of public health, nutrition and socio-economic development

nsg

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nsg

TRIPS Flexibilities and Domestic Policy Space: The Case of India

Prof. N.S. Gopalakrishnan
Centre for IPR Studies,
Cochin University of Science and Technology,
Cochin, Kerala, India

nsg

Introduction

- Subject matter of protection
- Pre-grant opposition
- Compulsory Licence
- Parallel import
- Exceptions
- Conclusion

nsg

Subject matter of Protection

- Subject matter of protection
  - Section 2(j) Invention
    - a new product or process involving an inventive step and capable of industrial application
- **Inventive step - Section 2(j(a)) (2005)**
    - Identification of a feature of an invention – "Claims"
    - Finding out whether there is "technical advancement" or "economic significance" or both in the feature of the invention
    - Examining whether it is obvious to a "person skilled in the art"

nsg

Pharmaceutical Inventions

- Pharmaceutical inventions – Section 2(ta) (2005)
  - Pharmaceutical substance means any **new entity** involving one or more inventive step
    - new entity with technical advancement or economic significance and not obvious to persons skilled in the art
    - Only ‘new molecules’ or other improved innovations as well?
    - If so what is the degree of improvement (technical advancement/economic significance)?

nsg

Pharmaceuticals

- **Section 3(d) - not inventions (2005)**
  - ″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.
    - *Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;".

nsg

Pharmaceuticals

- **Section 3(e) &(f) - not inventions (1970)**
  - a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
  - the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

nsg

Pharmaceuticals

- Is this reflect the standard of inventive step necessary to qualify “new entity”?
  - “Enhancement of non efficacy”
  - “Such known process results in a new product or employs at least one new reactant”
  - “They differ significantly in properties with regard to efficacy”
  - “resulting only in the aggregation of the properties”
  - “the mere arrangement or re-arrangement or duplication”

nsg

Pharmaceuticals

- Is this to exclude all kinds of improved inventions in the area of pharmaceutical substance?
  - Substantial improvement
  - Incremental improvement
  - Marginal improvement
- Freedom left to the judiciary to determine

nsg

Novartis Case

- ***Novartis AG v. Union of India and others*** (2007 Madras)
  - Challenged the constitutionality of section 3(d)
  - Violate of Article 14
  - Not complied with TRIPS Agreement
- Regarding non compliance the court held that domestic court has no jurisdiction
- Held that 3(d) not violative of Article 14

nsg

Cases of Inventive step

- *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries,* (1979) 2 SCC 511
- Is improvement patentable?
  - "It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an "inventive step". **To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before"**

nsg

Cases of Inventive step

- "The expression "does not involve any inventive step" used in Section 26 (1)(*e*) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of patent law. **The "obviousness" has to be strictly and objectively judged".**
- Need for higher standards of patentability

nsg

Pre-Grant Opposition

- Pre-grant opposition
  - Any person can file a opposition
  - Grounds of validity
  - Need to here the party
- Post-grant opposition
  - Within one year
  - Any interested person
  - Grounds of validity
  - Cancel the patent
- Helps to prevent grant of bad patents

nsg

Compulsory Licence

- Compulsory licence – General (s. 82 – s. 94)
  - Grounds (Section 84)
    - Reasonable requirement of public not satisfied
      - Industrial growth and development
      - Commercial working prevented by import of products
    - Not available at reasonably affordable price
    - Not worked in the territory of India
  - After 3 years of sealing of patent
  - Any person including a holder of a licence

nsg

Compulsory Licence

– Conditions of licence
  - Reasonable royalty
  - Commercial working with reasonable profit
  - Make available to the public products at reasonably affordable price
  - Non-exclusive and non transferable
  - Predominately to sell in Indian market
  - Central Govt. may permit import of the product

nsg

Special Compulsory Licence

- Special compulsory licence (Section 92)
  - In case of national emergency
  - Extreme urgency
  - Public non-commercial use
    - Immediately after sealing of patent
    - Notification by the Central Govt.
      - Licence based on application to the Controller
      - Manufacture and sale at lowest possible price
      - Following the normal procedure

nsg

Special Compulsory Licence

– Cases of public health crisis – Doha Declaration (s. 92.3)
  - AIDS, human immuno deficiency virus, tuberculosis, malaria or other epidemic
  - Issue compulsory licence without following the procedure of giving opportunity and to the owner and following the opposition procedure
  - Inform the owner as soon as may be practicable

nsg

Special Compulsory Licence

- Compulsory licence for export to countries without manufacturing capabilities – Doha (s. 92A)
  - Insufficient or no manufacturing capability
  - Compulsory licence from that country
  - Only to such countries based on such terms and conditions

- Provisions for Govt. use (s.99 – s. 103).
- Revocation of patent (s.66 & s.85)
  - On public interest
  - Non-working after issue of compulsory licence

nsg

Exceptions

- Parallel import (S. 107A)
  - Importation from a person duly authorized under the law to sell
- Use to generate information for drug approval
  - Bolar Exemption
  - Research exception (section 47)

nsg

Conclusions

- Used the flexibilities to limit the scope of patent – prevent ever-greening and maintain quality of patent
- Ensure drugs at affordable cost
  - Keep minor inventions in public domain
  - Public involvement in preventing grant of bad patents
  - Compulsory licence
  - Parallel import
- Responsibility of judiciary to maintain this balance to promote public health

nsg

Case Study – Pharmaceutical Patent Oppositions

Prathibha S
School on Trade and Public Health
Centad and IIFT
(6th October 2009)

GLEEVEC CASE – HISTORY

- Early 1990s: Ciba Geigy developed imatinib free base [In 1996, Ciba Geigy was taken over by Novartis].
- 1993: Novartis AG files US patent application for imatinib and its pharmaceutically acceptable salts, which is subsequently granted.
- In 1996 Zimmermann, one of the inventors conducted experiments on imatinib and imatinib mesylate and concluded that there is no significant difference between the two forms.
- 18 July 1997: Novartis AG filed a patent application for β-crystal form of imatinib mesylate in Switzerland
  - Imatinib mesylate = imatinib free base + methane sulphonic acid
- 17 July 1998: Novartis AG filed patent application for β-crystal form of imatinib mesylate in India claiming priority from Switzerland.
- 2001: Novartis AG received USFDA approval for *Gleevec* to treat chronic myeloid leukemia.

GLEEVEC CASE – HISTORY

- 2004: CPAA filed a writ petition before the Supreme Court challenging the grant of EMR to *Gleevec* and also the provisions relating to EMR.
  - [Withdrawn after rejection of patent application]

- March-April 2005: *Patents (Third Amendment) Act* passed and came into force.

- September 2005: CPAA filed a pre-grant opposition to Novartis' patent application.

- January 2006: Patent Controller rejected Novartis AG's patent application holding that the β-crystal form of imatinib mesylate is:
  - not novel,
  - does not involve an inventive step,
  - Is a crystalline form (imatinib mesylate) of an already known substance (imatinib) with no significant difference in efficacy

GLEEVEC CASE – MADRAS HIGH COURT

- May 2006:
  - Novartis AG filed a series of writ petitions challenging Patent Controller's order.
    - Subsequently, writ petitions converted to appeals.
    - April 2007: Notification by Central Government of Intellectual Property Appellate Board (IPAB) and transfer of all pending appeals to IPAB.
    - Appeal presently before the IPAB.
  - Novartis AG and Novartis India filed writ petitions challenging Section 3(d) of the *Patents Act, 1970* on the grounds of:
    - TRIPS non-compliance, and
    - Violation of equality provision (Article 14)
    - Violation of right to profession, trade and business (Article 19) [subsequently dropped]

GLEEVEC CASE – ARGUMENTS

- Novartis argued that Section 3(d):
  - is not in compliance with the TRIPS Agreement;
  - is in violation with the government's (non-enforceable) constitutional duty to harmonise its domestic laws with its international obligations;
  - is vague, arbitrary and confers uncanalised powers to the Patent Controller and therefore violates Article 14 as there is no clarity as to what the terms “efficacy”, “enhancement of efficacy” and “significant enhancement of efficacy” mean.
- Novartis prayed that if the court could not strike down Section 3(d) as TRIPS non-compliant, it should at least declare that Section 3(d) is not TRIPS non-compliant.

GLEEVEC CASE – ARGUMENTS

- Government, CPAA and other generic companies argued that:
  - Private companies such as Novartis cannot challenge a law as being TRIPS non-compliant.
  - Domestic courts do not have jurisdiction to decide whether a municipal law is TRIPS compliant or not. The appropriate forum is the WTO Disputes Settlement Body and this can be invoked only by a Member State.
  - Section 3(d) is not in violation the equality provision of the Indian Constitution as the concept of efficacy is well-known to persons in the pharmaceutical industry and it is impossible to lay down a "one size fits all" standard to determine what constitutes a significant enhancement of efficacy.

GLEEVEC CASE – JUDGMENT

- Issue of TRIPS non-compliance cannot be examined.
  - Domestic courts do not have jurisdiction to decide whether a domestic law is in violation of an International Treaty or not.
  - Exclusive forum for determining TRIPS-compliance is the WTO Disputes Settlement Body by a Member State.
  - Because it found that it lacked jurisdiction to decide such issues, the Court declined to address the issue of whether section 3(d) was in compliance with the TRIPS Agreement.
  - The Court refused to grant any declaratory relief.

GLEEVEC CASE – JUDGMENT

- Section 3(d) is not vague or arbitrary and therefore does not violate Article 14.
  - Concept of "efficacy" has a clear meaning in the pharmaceutical field.
  - Efficacy is to be understood as therapeutic efficacy.
  - Concept of "enhancement of efficacy" too has clear meaning in the pharmaceutical field. Therefore, a patent applicant can place on record the therapeutic effect/efficacy of a known substance and the enhancement in that known efficacy;
  - Parliament can use broad, undefined terms which are to be interpreted and applied by the Patent Offices in different factual circumstances.
  - "*We have borne in mind the object which the Amending Act wanted to achieve, namely … to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.*"

GROUNDS

- Standard patentability criteria – novelty, inventive step and industrial application

- Section 3 exceptions: Not patentable
  - 3(d) – new forms of known substance unless significant difference in efficacy
  - 3(d) – mere discovery of new property or new use of known substance
  - 3(e) – substance obtained by mere admixture resulting only in aggregation of properties

- Failure to inform Patent Controller of corresponding or similar foreign applications.

STATUS OF CIVIL SOCIETY OPPOSITIONS

Drug	*Opponent*	*Status*
Gleevec	Cancer Patients Aid Association	Application rejected
Combivir	MNP+	Application withdrawn
Atazanavir	INP+ and KNP+	Application deemed abandoned
Amprenavir agenerase	INP+ and UPNP+	Application deemed abandoned

STATUS OF CIVIL SOCIETY OPPOSITIONS

Drug	*Opponent*	*Status*
Valganciclovir	INP+ and TNNP+	Post and pre-grant pending before Patent Office
Tenofovir	INP+ and DNP+	1 opposition withdrawn 2 pending – {Rejected}
Kaletra (soft gel)	INP+	Application deemed abandoned
Lopinavir	INP+, DNP+ and NMP+	Pending

STATUS OF CIVIL SOCIETY OPPOSITIONS

Drug	*Opponent*	*Status*
Ritonavir	INP+ and DNP+	Pending
Abacavir sulfate	INP+	Application deemed abandoned
Efavirenz	DNP+	Post-grant opposition pending
Nevirapine hemihydrate	PWN+	Application rejected
Pegasys	Sankalp Rehabilitation Trust	Post-grant opposition rejected Appeal filed before IPAB

Other OPPOSITIONS

- Nevirapine Hemihydrate
  - relates to the suspension form of Nevirapine
  - used in the manufacture of pediatric dosages.
  - patent application filed by Boehringer Ingelheim Pharmaceuticals
  - opposition filed by Positive women Network and Indian Network for People living with HIV/AIDS
- Decision of the Controller
  - Application rejected on the following grounds
    - lack of inventive step as the aqueous suspension of Nevirapine hemihydrate can be prepared in a customary manner.
    - It is a combination of known substances with evidence to show enhanced efficacy. This squarely falls under Section 3(d) new forms of known substances – includes ***combinations*** .
    - That it is a mere admixture resulting in aggregation of properties. [Section 3(e)]

PEGASYS

- used for the treatment of the hepatitis-C virus
- an estimated 12.5 million people in India are infected with the hepatitis-C virus (HCV) .
- Left untreated, hepatitis-C can lead to liver cirrhosis, liver cancer or liver failure.
- Injecting drug users are especially vulnerable to HIV-HCV co-infection.
- marketed by F. Hoffmann-La Roche
- price of Rs 2.25 lakh (US$ 5,625) for a 6-month course
- Pegylated Interferon is post grant opposition. It was filed in May 2007

Pegasys

- Opposition filed by Sankalp Rehabilitation Trust on the following grounds:
    - Novelty
    - Inventive step
    - It is a mere admixture of known substances covered under Section3(e) of the Patents Act
    - It is just a “new form of a known substance” and is not patentable under section 3(d) of the Act.
- An Opposition Board was constituted. In our opposition, the Opposition Board found that there is no inventive step and section 3(d) has not been complied with.
- 8-9 September 2008: A hearing was held before Mr. T. V. Madhusudhan, the Assistant Controller of Patents and Designs.
- 17 March 2009: The Patent Office dismissed the oppositions and upheld the grant of patent to Roche. An appeal has been filed against this decision.

VALGANCICLOVIR

  - is an important treatment for active cytomegalovirus retinitis (CMV) infection and to prevent CMV infection in patients who have received organ transplants.
  - people living with HIV are susceptible to CMV.
  - the infection can lead to blindness without treatment.
  - CMV can be effectively treated with oral doses of valganciclovir consisting usually of 264 tablets given over four months.
  - Cost of treatment fixed by Roche is Rs. 2,74,560 per patient
- July 2006: INP and TNNP + filed a pre grant opposition against Valganciclovir and sought a hearing from the Patent Office.
- June 2007: The patent office, without hearing INP+ and TNNP+, granted a patent.
  - Thereafter, pharma cos and DNP+ filed a post-grant opposition.
  - In the meantime, Cipla launched generic version of Valganciclovir at less than 1/4th of Roche's price.
- Bombay High Court: Roche filed infringement suit against Cipla.

VALGANCICLOVIR

- Madras High Court:
  - INP+ and TNNP+ filed a WP in Madras High Court
- Pre-grant oppositions [Section 25]:
  - Any person can file prior to grant of a patent.
  - No fees are required.
  - Used by public-health groups to file oppositions to key ARVs and drugs to treat opportunistic infections and cancer
  - Controller shall grant a hearing to the opponent if requested.
- Procedure in Pre- grant Opposition [Rule 55]:
  - After consideration of the opposition if the Controller is satisfied that the patent shall be refused or has to be amended
    - The Controller shall give notice of the opposition to the Applicant
    - Applicant to file reply with statement of evidence (if any) within three months
    - After consideration of the opposition and submission during the hearing the Controller shall decide either to grant or reject the patent
- Judgment:
  - 2 December 2008: The High Court set aside the patent and directed that the opposition be heard by another patent official before 31 January 2009.
  - A hearing, if requested by the opponent, is a statutory right.
  - Failure to provide such hearing is violation of right to hearing[A facet of principle of natural justice]

VALGANCICLOVIR

- Supreme Court:
  - Roche filed SLP challenging Madras High Court's decision.
  - Supreme Court refused to grant stay to Roche and directed the Controller to decide the application and while deciding the controller has to consider the pre-grant opposition within 31 January 09.
  - The case was referred back to patent office.
- Madras Patent Office:
  - The Controller rejected our opposition, but did not decide the application.
- Back to Supreme Court:
  - INP+ and TNNP+ preferred an SLP.
  - 2 March 2009: The Supreme Court permitted INP+ and TNNP+ to file an affidavit in the post grant hearing of Valganciclovir. They also directed the Controller to hear and decide all the post grant opposition pending in this case with weeks from the date of the order.
  - Supreme Court also directed that Roche will not seek an injunction on for this patent in the Court. The case is coming on 6.7.2009
- Back to Patent Office

Thank You

AN OVERVIEW OF PUBLIC HEALTH ISSUES IN INDIA

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Presented at The Centad-IIFT School on Trade and Public Health, 5th -9th October 2009

Outline of presentation

- Defining public health
- Role of health services in public health
- Socio-economic determinants of health
- Health services as a determinant of health
- A systems approach to health services
- Defining the sub systems of the health services
- What are the systemic inadequacies in the health services in India?
- Role of market and state mix in health services

Outline of presentation

- Health outcomes in a stratified society mirror inequities
- Health inequities as an outcome of the socio-economic and health service inequities
- What are the forms of health inequities- regional, caste, class and gender

Outline

- Persistence of poverty and class-caste-gender inequities
- Inequities in access to health services=preventive and curative services
- Health services perpetuating inequities in India
- Period of rapid economic growth and efforts to address health and health service inequities
- Are these initiatives adequate to address inequities?

Social Determinants of Health

- Socio-economic and health service factors are important determinants of health
- Often health services and medical technology are given primacy
- Evidence show that health services are only one of the inputs for improvement of health status
- In highly stratified societies like ours, health outcomes vary across income, caste and gender

Health situation in India

- **Poverty in India – Key Indicators**
- ● 836 million Indians are poor and vulnerable
- ● India is placed 126**th** out of 177 countries on the United Nations Human Development
- Index, which ranks countries on how well they ensure health, education and decent living standards.
- ● Maternal Mortality and Infant Mortality rates in India's poorest districts are worse than sub-Saharan Africa
- ● India has the largest number of people in any country in the world without access to education
- ● Poverty in India cannot be overcome without dramatically expanding and improving access to and quality of public education, health, water and sanitation.

Source: Imrana Qadeer-Wada Na Todo Abhiyan

Health in India : Key Indicators

- ● India accounts for more than 20% of global maternal and child deaths, and the highest maternal death toll in the world estimated at 138,000.
- ● Infant Mortality Rate (IMR) in India was 67.6 in 1998-99 and has come down to 57 in 2005-06. Kerala heads the progress made so far with an IMR of 15/1000 births. Uttar Pradesh has the worst IMR in the country of 73/1000 births.
- ● Maternal Mortality Rate (MMR) is currently 4 deaths per 1000 births. India accounts for the largest number of maternal deaths in the world.
- ● 79% of the children between the age of 6-35 months, and more than 50% of women, are anaemic, and 40% of the maternal deaths during pregnancy and child-birth relate to anaemia and under-nutrition.

Source: Wada Na Todo Abhiyan-Imrana Qadeer

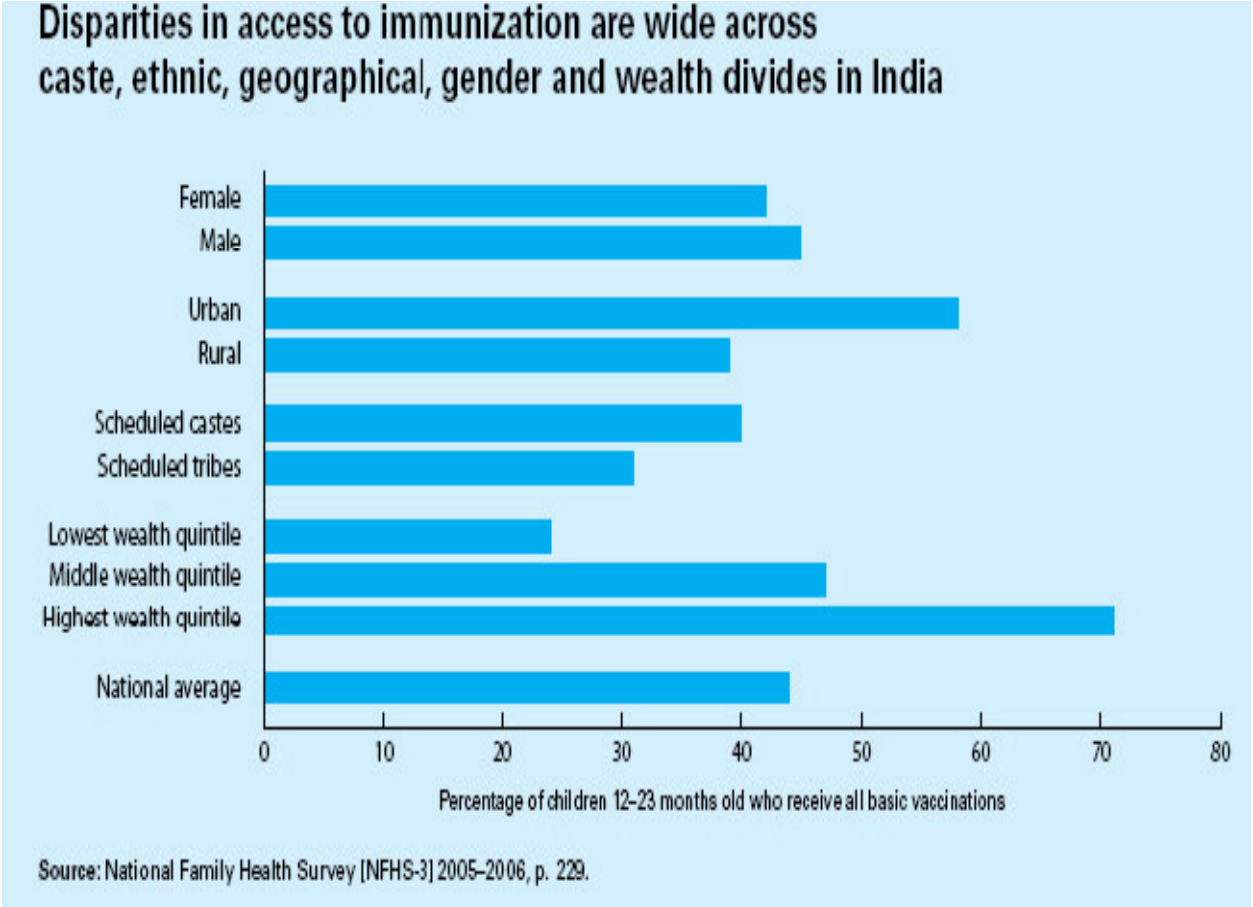
Inequities in Health Indicators

- All India averages mask inequities
- There are rural-urban; inter and intra state; class, caste and gender inequities
- If Infant Mortality Rate is disaggregated across rural-urban and selected states the variations are apparent
- Kerala has the lowest of 15 per 1000 live births- 14 (R) and 18 (U) while Uttar Pradesh has the highest of 73 per 1000 live births- 75 (R) and 64 (U).

Inequities in Health Outcomes

- The Under 5 Mortality Rate shows marked variations across caste, class and gender
- The Schedule Caste and Schedule Tribe have worse indicators compared to other caste groups
- The gender differential is also marked with females having a higher mortality compared to males
- The pattern of these inequities can be explained in terms of socio-economic conditions
- Health services can play an important role in reducing or perpetuating these social inequities

Disparities in Access to Preventive Services



Why these inequities in access to health services?

- The structure and organisation of health services is responsible for perpetuating inequities in access
- United Nations calculations show that India's spending on public health provision, as a
- share of GDP is the 18**th** lowest in the world.
- Nearly 67% of the population in India do not have access to essential medicines.
- There are 585 rural hospitals compared to 985 urban hospitals in the country.
- Out of the 6,39,729 doctors registered in India, only 67,576 are in the public sector.

Systemic Barriers in the Health Services

- Need for a systems perspective to analysing barriers
- The sub systems of the health service system- financing, provisioning, medical and paramedical education; drugs and technology; research.
- Underfunding of public sector
- Unregulated growth of commercial sector
- Public –private mix across sub systems in the health service system
- Lack of accountability and variable quality in public and private sectors

Recent initiatives for correcting these systemic inequities

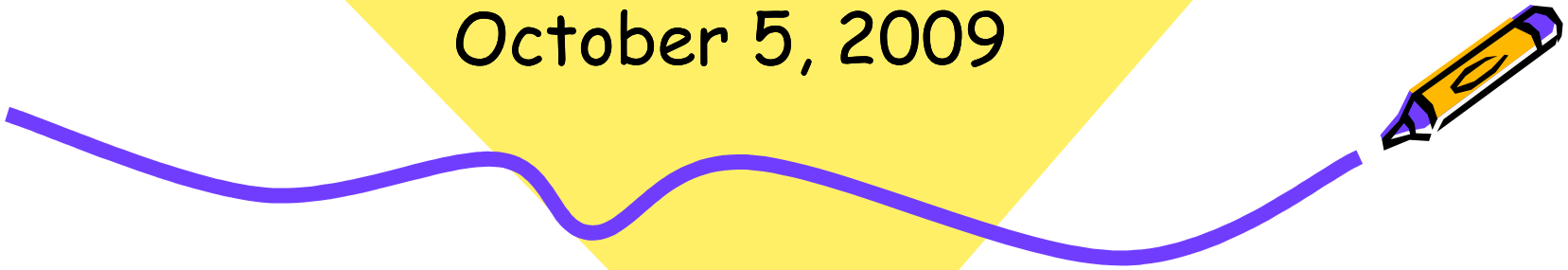
- Over the last six decades there is a recognition of systemic inequities
- The efforts to address has been piecemeal
- Unfettered growth of markets and a stunted public sector is an important reason
- Health is low on the political agenda
- Examples of recent initiatives include NRHM; JSY; RSBY; NUHM
- All these are centrally directed in a mission mode

Are these adequate?

- There are limits to targeted programmes
- Not enough attention to regulate the private sector across different sub systems of the health service system
- The abdication of public services by the middle and upper middle classes

Trade in Services and Impact on Public Health

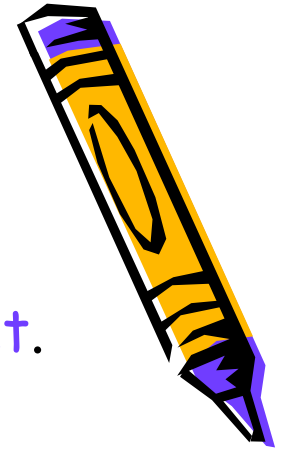
October 5, 2009



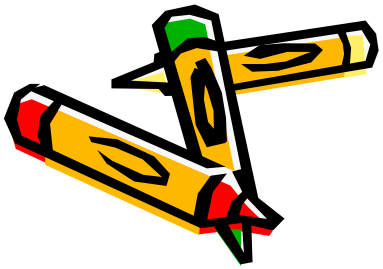
Some well-known instances ..

- Former Argentinean soccer superstar Diego Maradona went to Cuba for drug treatment.
- Sachin Tendulkar underwent a surgery on his left elbow in London, as he was suffering from Tennis Elbow problem.
- Ex-Palestinian President Yasser Arafat visited France for medical treatment.
- Is it only the dignitaries who travel abroad for treatment?? NO, it is very much common for civilians as well.
- Reports of patients from other developing countries coming to India for complex operations often heard.

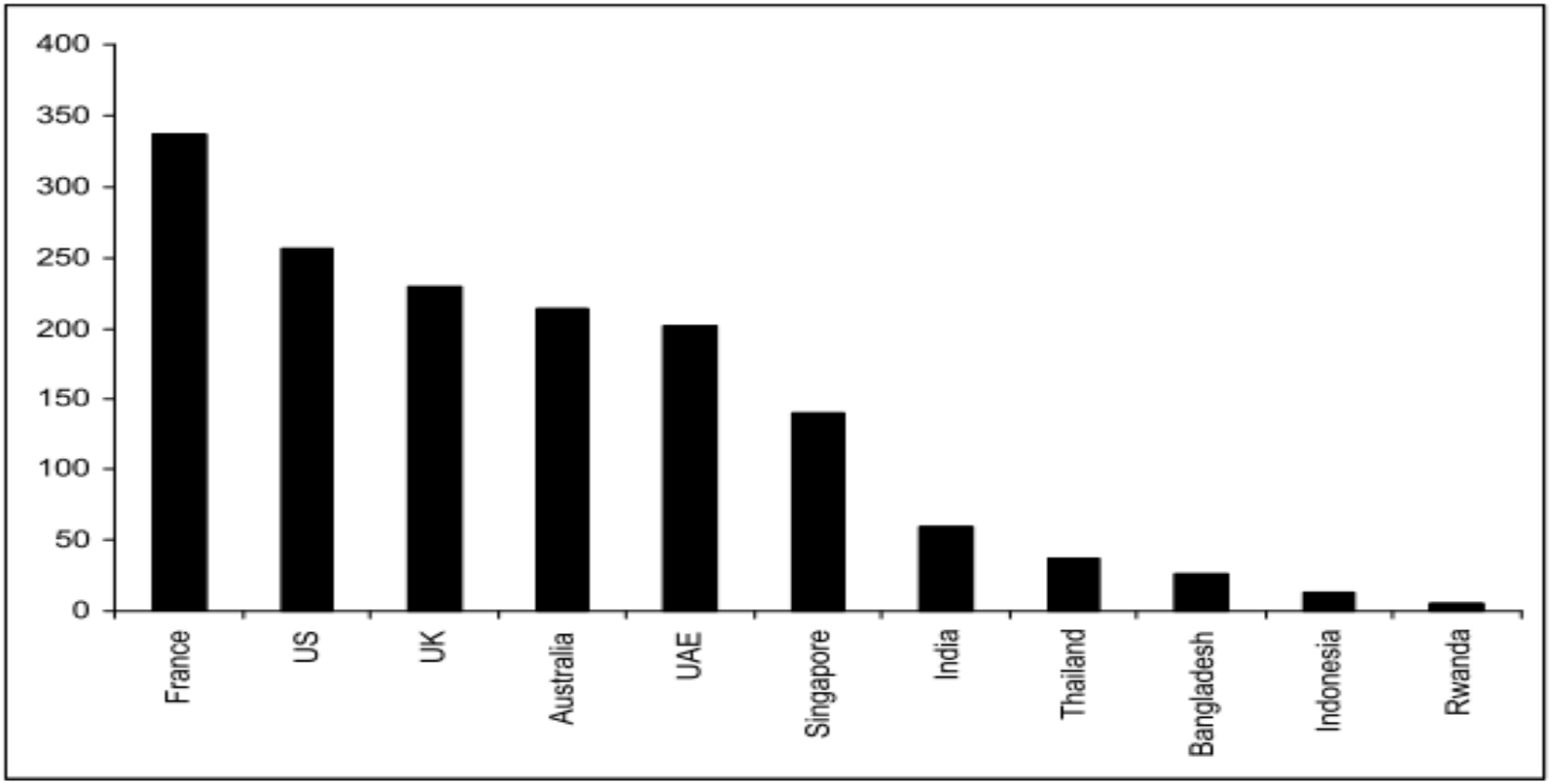
Trade in Health Services



- Basis of trade: Endowment effect and Price effect.
- Implication: greater foreign exchange earning opportunities for the country.
- Need to understand the potential conflict between public health policy of a country and export earning opportunities.
- Creation of endowment / infrastructure implies cost for Public Funds. However, net outflow of resources (e.g. – doctors, nurses) is likely to adversely affect the local citizens.
- Demand and supply capability mismatch - inflow of foreign patients may enhance the cost of services, causing hardship for the local citizens.



Endowment Effect: Physicians per 100,000 people in Select Countries



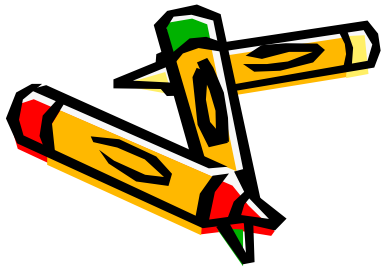
Source: Human Development Report (2007)

However, it is observed that doctors are actually moving from developing countries like India and Thailand to developed countries like EU countries and US. The higher remuneration opportunities play the driving force here.

Price Effect: Costs of some treatment in select countries (in US$)

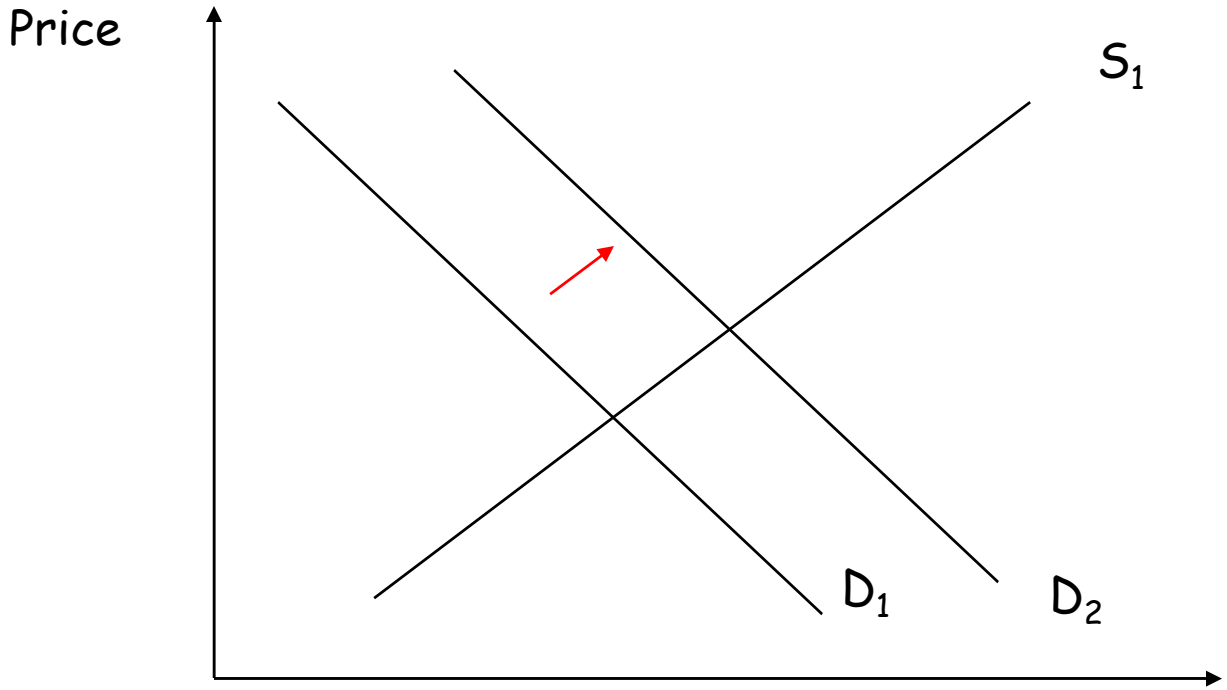
Operation	Thailand	India	Singapore	US	UK
Heart bypass graft surgery	7894	6000	10417	23938	19700
Heart-valve replacement	10000	8000	12500	200000	90000
Angioplasty	13000	11000	13000	31000 - 70000	-
Hip replacement	12000	9000	12000	22000 - 53000	-
Hysterectomy	10000	-	13000	-	-
Bone-marrow transplant	-	30000	-	250000 - 400000	150000
Liver transplant	-	40000-69000	-	300000 - 500000	200000
Neurosurgery	-	800	-	29000	-
Knee surgery	8000	2000-4500	-	16000-20000	12000
Cosmetic surgery	3500	2000	-	20000	10000

Smith et al (undated)



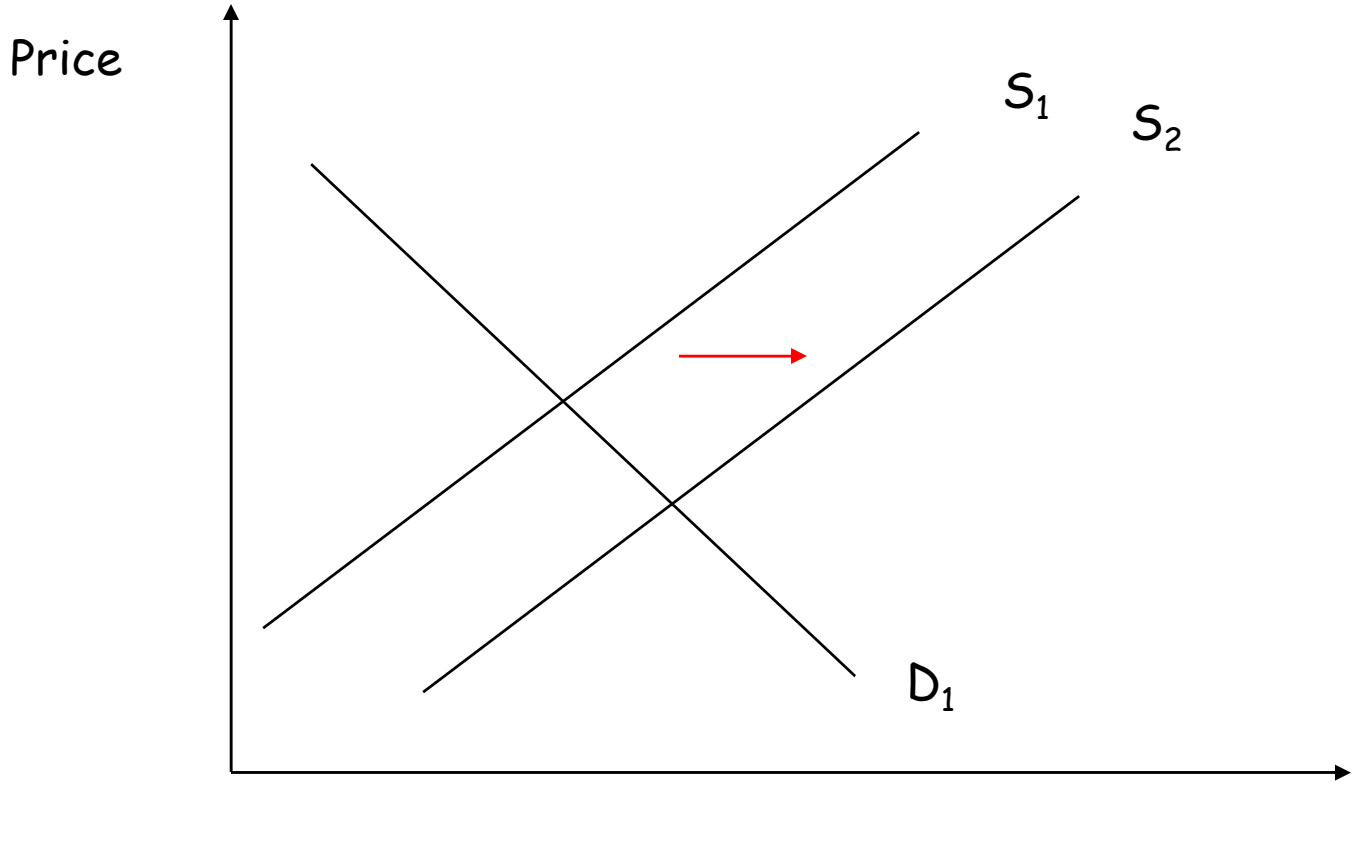
Here a movement of the patients from the developed to the developing countries could be observed, so as to reap the benefits of the lower cost structure.

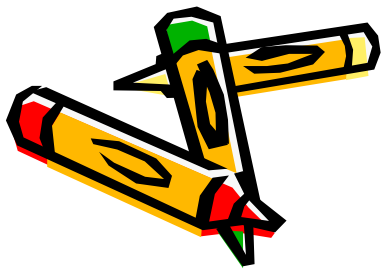
The Demand Effect



If there is an inflow of foreign patients in a country, without increase in the infrastructure, the cost of health services may go up.

The Supply Effect



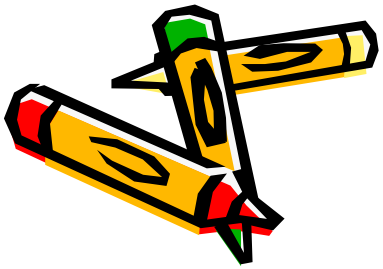


If there is an inflow of foreign funds to create health infrastructure, the cost of health services may go down. However that is not necessarily true.

Trade in Health Services within the GATS Framework

GATS Sectoral Classification	Definition
Professional services	
a. Medical and dental services	Services chiefly aimed at preventing, diagnosing and treating illness through consultation by individual patients without institutional nursing
b. Services provided by midwives, nurses, physiotherapists and paramedical personnel	Services such as supervision during pregnancy and child-Birth, nursing (without admission) care, advice and prevention for patients at home.
Health Related and Social Services	
a. Hospital services	Services delivered under the direction of medical doctors chiefly to in-patients aimed at curing , reactivating and/or maintaining health status
b. Other human health services	Ambulance services; residential health facilities services other than hospital services; and other human health services (pathology, virology, blood collection etc.)

Source: Mortensen (2008)

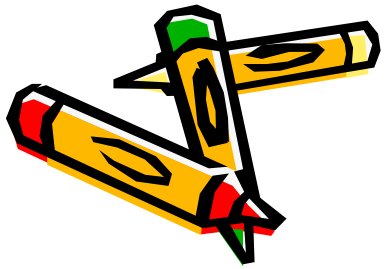


There are 12 sectors (Business service, Communication service, Education service etc.) and 161 sub-sectors (Business service – Legal service, Computer and related service etc.) in GATS.

Four Modes of Trade in Services

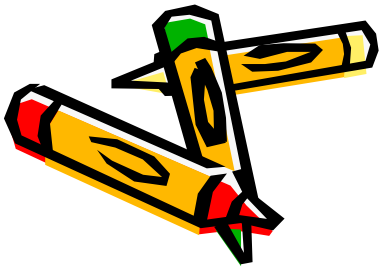
Mode of Supply	Definition	Examples of health services	'Carriers'
Mode 1	*Cross-border Supply*: suppliers resident in one country provide services in another country without physical movement of neither supplier nor consumer	Tele-health	Telecommunication networks, regular mail
Mode 2	*Consumption Abroad*: consumers resident in one country travel to the country of suppliers to consume a service	Medical Tourism	People or firms
Mode 3	*Commercial Presence*: firms (legal persons) moving to the location of consumers through the establishment of a foreign affiliate or branch	Hospitals or clinics	Firms
Mode 4	*Movement of Natural Persons*: individual suppliers traveling temporarily to the country of the consumers to provide a service	Doctors or nurses working temporarily outside their country of origin.	People

Source: Mortensen (2008)



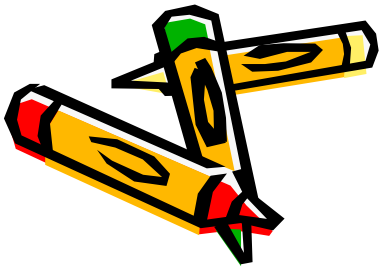
How Negotiations take place within GATS?

- Request-Offer Approach
- Request by trade partners in areas with good supply and export capacity, removal of sector-specific barriers
- Analysis of the requests received in consultation with local stakeholders - Consideration of the benefits of allowing a foreign service provider within a sector
- Preparation of a 'offer' that provides the maximum market access it can provide to all other members.
- Done in a sector-by-sector basis, then mode-by-mode in each sector
- National Treatment and Market Access limitation



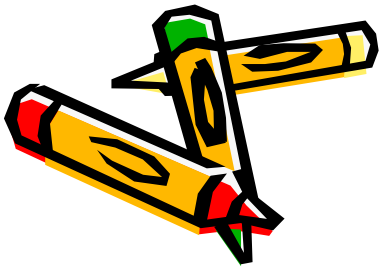
Mode 1

- Mode 1 is growing rapidly in recent period.
- It includes both low end high end transactions.
- Low end: Medical Transcription (MT) of an US doctor's voice message by a person sitting in India / other English-speaking country.
- High end: Multi-country video-conferencing over the critical condition of a patient during heart transplant etc.
- Time dimension: 'Real time' (i.e. - immediate consultation) and Store-and-forward' (e.g. – tele-cardiology, tele-pathology and tele-diagnostic services) model.
- Health Insurance Portability and Accountability Act (HIPAA) governs outsourcing of MT work – the idea is to enable security and confidentiality of information.
- India, Philippines and Cuba are the market leaders in this segment, aided by low-salaried, English-speaking educated professionals.
- India is slowly moving up the value chain. In recent years Medical billing and collection and medical claims processing has increased in India.



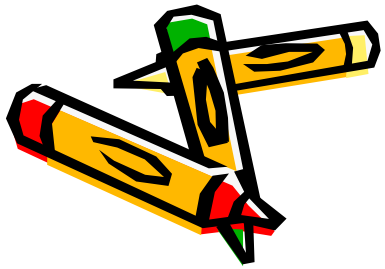
Mode 1 …

- The need to employ qualified professionals is increasing.
- For instance in Philippines, medical-transcription is done by medical college graduates who work part time while studying. Many of these companies are owned by US investors.
- In India a number of colleges are emerging for offering certificate / diploma for medical transcription.
- Many Indian firms offering insurance service are currently becoming HIPAA compliant.
- Apollo Group provides tele-medicine services (consultation, diagnostic, telepathology, teleradiology, etc) to patients in Bangladesh, Nepal, Bhutan, and Burma, Kazakhstan etc.



Mode 2

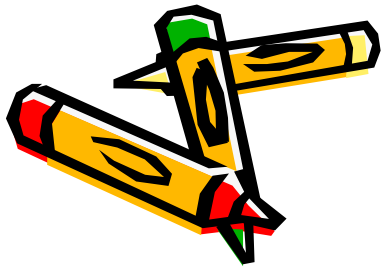
- Involves inflow of patients in the cheaper treatment location.
- Also known as 'health tourism' - increasing in recent period thanks to the increased transparency in visa granting, greater connectivity etc.
- Social, cultural, and linguistic factors play a key role in determination of the patient flow.
- For instance, a major proportion of the patients going to Cuba are mainly from the Caribbean and Central America; the same going to Jordan are mostly from Yemen, Bahrain, Sudan, Syria, Libya Saudi Arabia etc.
- A similar picture emerges in major ASEAN countries in general, barring the exception of Thailand, where Japanese patients have significant presence.
- In India a number of South Asian patients come every year.
- Health tourism in Kerala is a good example (e.g. – Ayurveda, Allopathic treatment etc.)



Health Tourism in ASEAN

Country	Export revenues	Number of patients	Origin of patients
Malaysia (2003)	RM 150 million ($40 million)	More than 100,000	60 percent from Indonesia, 10 percent from other ASEAN countries
Singapore (2002)	$420 million	210,000	45 percent from Indonesia, 20 percent from Malaysia, 3 percent from other ASEAN countries
Thailand	Around 20 billion baht in 2003 ($482 million)	470,000 (2001) 630,000 (2002)	42 percent from the Far East (mostly Japan), 7 percent from ASEAN countries

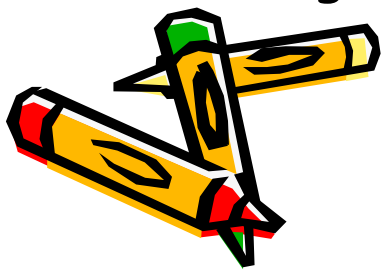
Source: Arunanondchai and Fink (2007)



Within this segment, linking the tourism sector with medical expertise is a common feature. Thailand is a good example of this phenomenon.

Mode 3

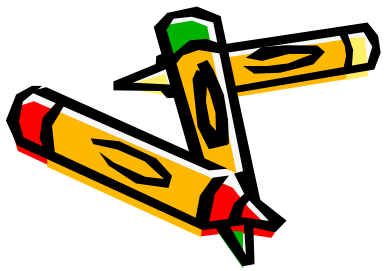
- This involves FDI flow in healthcare sector – includes both Acquisition and Greenfield investment possibilities.
- Beneficial if net addition to capacity occurs.
- However, internal migration and rising cost of services owing to privatization may not be ruled out.
- The driving motive is generally profit-related.
- Indonesian experience - limiting the investment at a particular scale.
- US and Germany are the global investors.
- In Southeast Asia, China and Singapore are the major sources of investment.
- India is witnessing a FDI flow in both directions.
- Investment inflow is witnessed both in hospitals and the diagnostic centres.



Activities of German and US foreign affiliates in health and social services

	Germany	USA
Number of affiliates abroad	148	17
Sales of affiliates abroad (US$ million)	3580	384
Employees of affiliates abroad (thousands)	34	3·3
Assets of affiliates abroad (US$ million)	5284	556

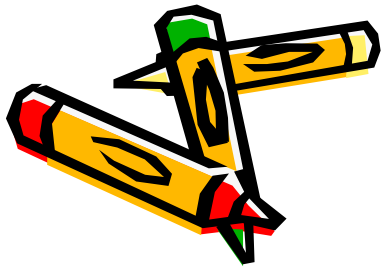
Source: UNCTAD FDI/TNC database.



Select FDI Approvals in Indian Hospitals

Sl. No.	Date	India Company	Origin of investment	Foreign Equity (US $ Mn.)
1	December 2002	Sir Edward Dunlop Hospitals, New Delhi	Canada	26.71
2	August 2004	Add Life Medical Institute Ltd. Sterling Hospital Building, Ahmedabad	USA	7.07
3	January 2004	Max Healthcare, New Delhi	Mauritius	6.63
4	October 2001	Malabar Institute of Medical Sciences Hospital Ltd., Calicut	UAE	2.97
5	July 2002	Peoples General Hospital Ltd., Bhopal	UAE	1.53

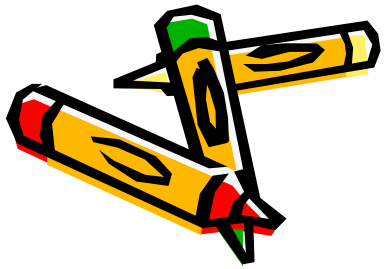
Source: Chanda (Undated)



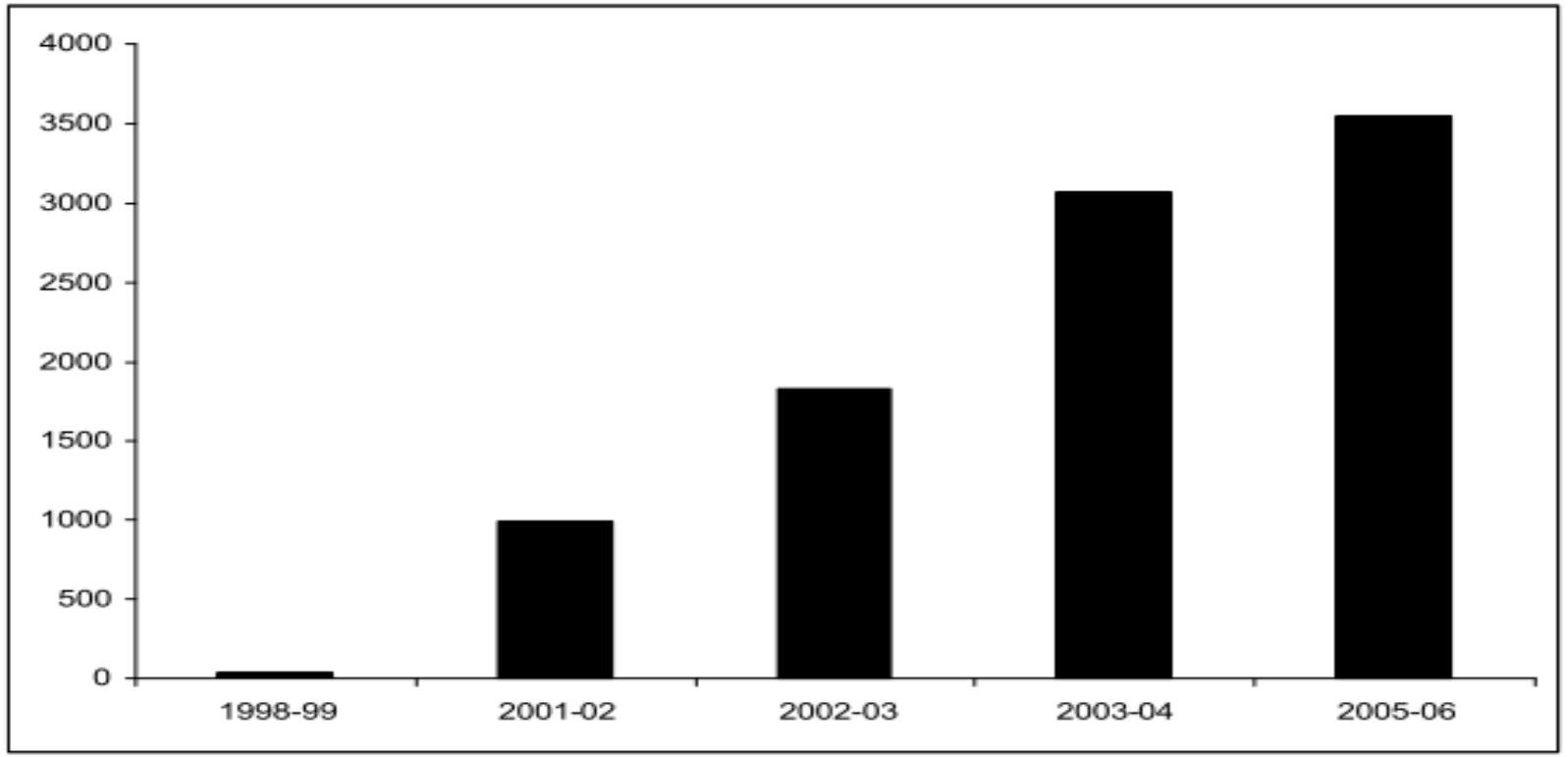
On the other hand, Apollo Group offers several services through franchises and partnerships in UAE, Saudi Arabia, Oman, Kuwait, Mauritius, Tanzania, UK, Sri Lanka, Bhutan, Nigeria, Bangladesh and Kazakhstan.

Mode 4

- The simultaneous inflow and outflow of professionals is more pronounced.
- Includes doctors, nurses, immigrant pharmacists, physician assistants, clinical laboratory technologists etc.
- The colonial and linguistic links acted as a major determinant of this flow. Price is the other determinant.
- Europe and US are among the major destinations.
- Movement of Indian doctors has increased over the last decade.
- Increase in the demand for nurses has also increased, given the ageing of population in the west.



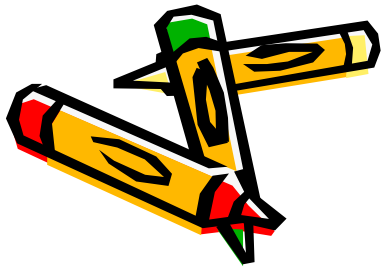
Registration of Indian Nurses in UK (2002)



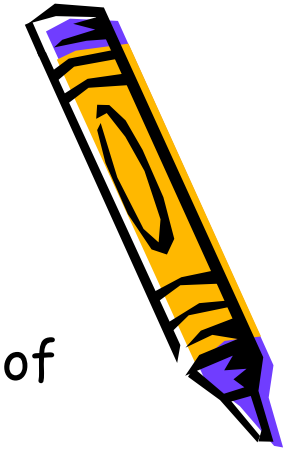
Source: Healey (undated)

Mode 4 ..

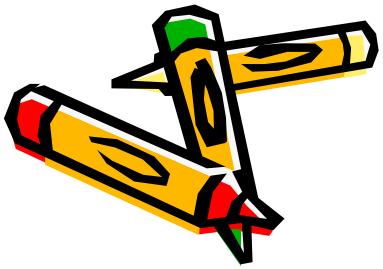
- Filipino and Indian nurses regularly find assignments in the West.
- It is observed from various estimates that the number of Philippine nurses working in Europe, US, West and Southeast Asia is around 87,000.
- Usually the hospitals and specialized recruitment agencies in destination countries directly source their nurses from Philippine's labor market.
- In response to the market forces, the medical schools in Philippines are adapting their course curricula in line with the requirement of the foreign markets.
- One interesting phenomenon in Mode 4 category is the both-way trade due to wage disparity.
- For instance, while Malaysian hospitals hire Indian and Filipino nurses, Malaysian nurses work in Singapore and Saudi Arabia.
- A similar scenario is observed for doctors and physicians in Malaysia as well.



Barriers on Services Trade



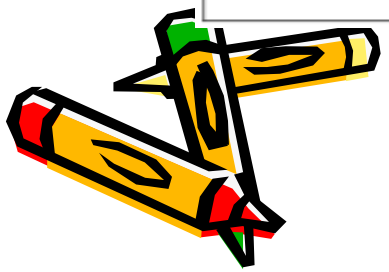
- Mode 1: ensuring security of information, qualification of the employees etc.
- Mode 2: Portability of medical insurance, restrictive conditions for private insurance schemes with respect to standards of care, patient safety, recognition of qualification, legal liability etc.
- Mode 3: limited commitment on opening the market for foreign investors.
- Mode 4: lack of mutual recognition of qualifications, visa regime, economic needs test (ENT), annual quotas, fluency in local language test etc.
- Lower level of commitments at the WTO negotiations is another problem.



Attempt to correct barriers through RTA route: Thailand, in its negotiations towards a free trade agreement with Japan, has requested that Japan's public medical insurance system cover the treatment of Japanese patients in Thai Hospitals.

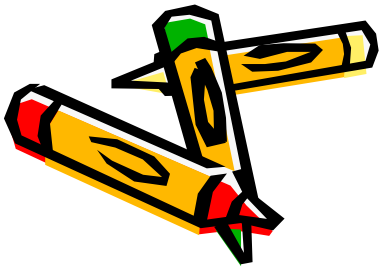
Service Barriers in ASEAN: Health Service (Mode 3)

	Explicit policy	GATS commitments
Cambodia	Full foreign ownership allowed; one director must be Cambodian.	No restriction, except at least one director for technical matters must be Cambodian.
Indonesia	Conflicting policies; full foreign ownership allowed according to investment policy; 90 percent foreign equity limitation according to Ministry of Health.	Unbound.
Laos	Full foreign ownership allowed.	Laos is in the process of acceding to the WTO. US-Laos BTA grants full market access and national treatment for health and medical care services.
Malaysia	30 foreign equity limitation (though foreign equity in one hospital exceeds 30 percent); economic needs test; minimum of 100 beds.	30 percent foreign equity limitation; economic needs test; minimum of 100 beds.
Philippines	Foreign equity ownership limited to 40 percent for hospitals; full foreign ownership allowed for health maintenance organizations.	Unbound.
Thailand	Foreign equity ownership limited to 49 percent; can be circumvented by assigning "nominees"; compliance with local regulations required.	Unbound.
Vietnam	Full foreign ownership allowed in principle; economic needs test; transfer of technology and training of local staff required.	US-Vietnam BTA commits Vietnam to full foreign ownership, but sets minimum investment requirements. Vietnam is in the process of acceding to the WTO. Third offer in services reflects commitment under the BTA.

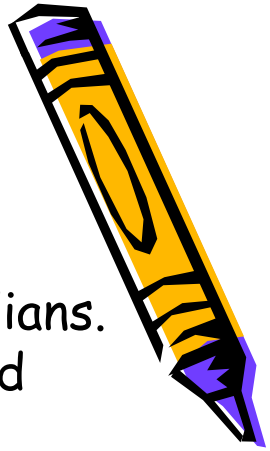


Service Barriers in ASEAN: Health Service (Mode 4)

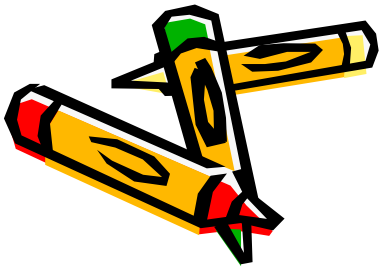
- In Malaysia and the Philippines entry of foreign medical professionals is subject to economic needs tests. Certain professions, such as dentistry, are completely closed to foreign professionals.
- Indonesia is largely closed to the entry of foreign healthcare workers. Limited exceptions only exist for occupational therapists.
- Market access in these countries is also granted on a preferential basis. For Malaysia, preferences take the form of bilateral agreements for the supply of nurses (with Albania, Bangladesh, India, Indonesia Myanmar, the Philippines, and Vietnam). Similar situation prevail in case of the Philippines.
- Entry of foreign healthcare workers to the Philippines is also subject to visa quotas set annually by the Department of Foreign Affairs.
- Thailand is, in principle, open to the entry of foreign professionals. However, entry is limited as they would need to pass a professional examination in Thai language.
- Malaysia has made a mode 4 commitment under the GATS for a number of specialized medical professions (e.g., forensic medicine, neurosurgery, cardiothoracic surgery, plastic surgery). Cambodia, Indonesia, the Philippines, and Thailand did not make GATS commitments relating to the movement of health professionals.



Indian experience in UK

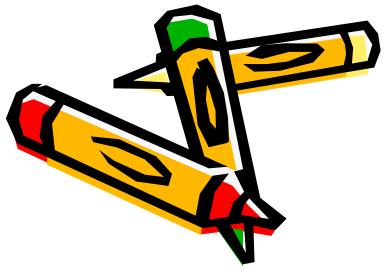


- In UK around 13000 of the 16000 non-EU Doctors are Indians.
- Earlier an apprentice after clearing the medical exam could continue upto getting a job offer.
- However a new Immigration Law was tabled in April 2006 to provide preference for Doctors coming from East Europe for Work Permit Visa.
- As a result of the regulation, if the student do not get a job offer within the visa period, he / she need to go back.
- The British Association of Physicians of Indian Origin (BAPIO) lodged a case at London High Court.
- The plea has been rejected in February 2007.
- It was later decided that new Immigration Law will not be applied immediately – but in future jobs will come to Indian doctors only if no doctors from other EU Member countries is found to be suitable.

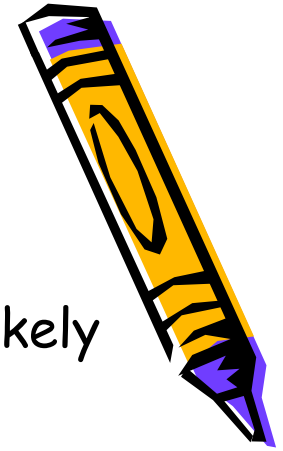


Expected Gains

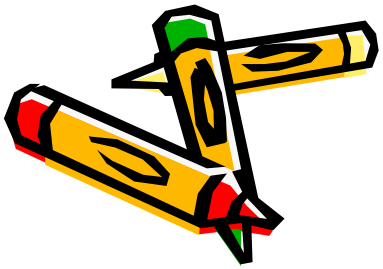
- Lower cost implications through travel abroad or outsourcing of medical transcription facilities to foreign service providers.
- Availability of greater choice, with entry of foreign players / options to go to foreign countries.
- Foreign investment inflow in hospital and related services can help a developing country in overcoming the capacity constraint.
- Creation of newer hospitals with foreign funds and doctors bridges the pre-existing shortage.
- The procurement of advanced medical knowledge and specialized equipment, may also help them in offering newer treatments to domestic patients.
- Efficiency also increases as better organizational skills and managerial know how is brought by the foreign firm.



Concern areas



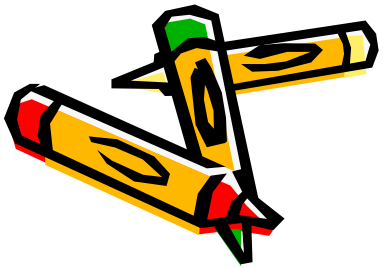
- Focus on export, especially in developing countries, is likely to inflict pressure on the supply capacity and the local population might get hurt in the process.
- Foreign-financed hospitals may entirely target the middle and upper income patients in urban areas and bypass the social health insurance schemes.
- The higher salary offered to the doctors attracts medical personnel away from public and private hospitals serving only local patients. This leads to shortages in public sector and in rural areas (i.e., internal brain drain).
- In many countries two-way movement of health professionals always creates shortage of medical personnel.
- The medical brain drain has seriously affected the Millennium Development Goals in many sub-Saharan African countries.



Opportunities and risks of trade in health services: Summary

Area of Trade	Opportunity	Risk
Mode 1	Increased care to remote and underserved areas	Diversion of resources from other health services
Mode 2	Much-needed foreign exchange earnings for health services	Crowding out of local population and diversion of resources to service foreign nationals
Mode 3	Opportunities for new employment and access to new technologies	Development of a two-tiered health system with an internal brain-drain
Mode 4	Economic gains from remittances of health-care personnel working abroad	Outflows of health personnel, with lost skills and investment in education of personnel

Source: WHO (2006)



Some African countries adopt carrot-and-stick measures for preventing migration, e.g. – by bonding newly-trained graduates to undertake a specified tenure of compulsory service at local hospitals, by offering economic incentives like scholarships and career advancement opportunities etc.

Indian Pharmaceutical Industry: In Retrospect and Prospect

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What is Pharmaceutical Industry?

- **Formulations**
- **Intermediates and Bulk Drugs**
- **Other products**
  - **Medicated bandages and dressing s; medical devices such as syringes; blood products; glands, organs and extracts of them.**
- **There are Indian and foreign private firms producing these products**
- **Indian public sector – (5)**

Evolution of Indian pharmaceutical industry

- **Evolution of Indian pharma industry cab be traced to Bengal Chemicals and Pharmaceutical Works (BCPL) in 1901.**
- **World Wars gave fillip to the domestic pharmaceutical sector**
- **During First World War Indian firms were successful in developing a few drugs that were of high demand at that time.**
  - **Production of caffeine from tea and surgical dressings.**
  - **Indigenous production met 13% of requirement in 1939.**

Evolution of Indian pharmaceutical industry…..

- **A number of new firms came up during the Second World War**
  - **Unichem, Chemo pharma, Indo Pharma, Indian Process Chemical Laboratory, Bio Chemical and Synthetic Products, etc.**
  - **Production of formulations based on imported bulk drugs.**
  - **The process development for the manufacture of Penicillin by Dr. Ghosh in West Bengal was a landmark in indigenous technological development.**
  - **Indigenous production met 70% of the requirement of the country in 1943.**

Current Status

- **One of the largest in the world in terms of production. Ranks 4th in terms of quantity and 13th in terms of value.**
- **Major contributor to the Indian export basket. Accounts for 2% of merchandise exports worth US$ 5381.6 million in 2007-08.**
- **Produces and supplies drugs at prices lowest in the world.**

Production

- **Production has been guided by the Industrial policy and Patent policy.**
- **A survey was conducted in 1948 on country's industrial potential in all sectors and in the pharmaceutical sector it was found that India was lacking resources especially in terms of technology and knowledge.**
- **This necessitated a liberal approach towards the foreign sector. Government's policy of industrialisation by way of import substitution was not made applicable to drug industry in the initial period, because there was no other alternative available to drug technology held by the foreign companies**
- **Industrial Policy Statement of 1948 states, “it should be recognised that participation of foreign capital and enterprise particularly as regards industrial technique and knowledge will be of value to the rapid industrialisation of the country”.**

Production…

- **Impact:**
  - **Influx of foreign firms. They acted as mere trading agents without engaging in any local production.**
  - **No indigenous production from basic stage by the domestic sector. Indian firms engaged in processing of imported intermediates and bulk drugs into formulations.**
- **Bhatia Committee (1954). The Committee recommended:**
  - **Indigenous production from basic stage**
  - **Restrict foreign firms**
  - **forbid deals that restrict sale of bulk drugs to non-associate firms.**
  - **Revoke product patent rights**

Production…

- **Pharma sector was brought under the purview of Industries (Development and Regulations) Act 1951.**
  - **Firms had to obtain licenses for the production of drugs.**
  - **Indigenous production of drugs has grown from Rs10 crore in 1947 to Rs 35 crore in 1952 and to Rs168 crore in 1965-66.**
- **Though there had been an expansion of production in pharmaceuticals, the dependence on imports did not decline. A large number of essential drugs and raw materials, penicillin, streptomycin and other antibiotics, sulpha drugs, glandular products and anti-leprosy drugs were imported.**
  - **Indigenous production had been affected by the product patent regime prevailed at that time.**

Production…

- **There was a need to control foreign monopoly.**
- **Monopolistic and Restrictive Trade Practices Act 1969.**
  - **Company with more than Rs 20 crore turn over is monopolistic and required prior permission for new undertaking, expansion, merger, takeover and appointment of directors in select cases**
- **Patents Act 1970.**
  - **Only process patents in pharmaceuticals**
  - **Period of protection was reduced from 14 years to 7 years**
  - **Local production of patented subject matter was mandatory**
  - **Impact: medicines were made available in India within 5 years of their introduction in the world market. E.g.. Ranitidine (anti-ulcer) – 1983 (world), 1985 (India). Norfloxacin (antibacterial) – 1984 (world), 1988 (India).**

Production…

- **Foreign Exchange Regulation Act 1973**
  - **Required all foreign firms to bring down their shareholding to below 40%.**
  - **Impact:**

Foreign Equity	No. Companies	
	1973	1985
100%	10	2
50-99%	24	12
40-50%	15	20
26-40%	11	10
Below 26%	6	22
Total	66	66

Production…

- **Drug Policy 1978**
  - **All firms were required to produce bulk drugs indigenously from basic stage.**
  - **These firms also had to supply 50% of the total production of bulk drugs to non-associated formulators.**
  - **Loan Licensing was prohibited**
  - **It restricted value of formulation to be 5 times the value of their total bulk drug production.**
  - **foreign firms with turn over in drugs exceed Rs5 crore per year to have R&D facilities in India. They were required to spend at least 4% of their turnover as recurring expenditure**
- **Impact of all these policies:**
  - **Production increased from Rs 168 crore in 1965-66 to Rs 1440 crore in 1980-81.**
  - **Share of domestic sector increased from 27% in 1975-76 to 52% in 1980-81.**

Production…

- **Drug Policy 1986**
  - **Encouraged higher production of bulk drugs. Introduced a graded system of ratio parameter for the production of bulk drugs and formulations.**
    - **FERA Companies – 1:4**
    - **Companies with production up to Rs 10 crore – 1:10**
    - **Companies with production between Rs 10 and Rs 20 crore – 1:7**
    - **Companies with production in excess of Rs 25 crore – 1:5**
  - **Impact:**
    - **Production of formulations increased from Rs 1200 crore in 1980-81 to Rs 6900 in 1993-94 (increase by 5.75 times)**
    - **Production of bulk drugs increased from Rs 240 crore in 1980-81 to Rs 1320 in 1993-94. (increase by 5.5 times)**

Production…

- **Drug Policy 1994**
  - **Abolished industrial licensing**
  - **Abolished the ratio parameters linking bulk drugs and formulations production**
  - **Permitted 100% foreign equity holdings and automatic approval of foreign technology agreements**
  - **new drugs which have not been produced elsewhere, if developed through indigenous R&D, would be put outside price control for a period of 10 years.**
- **Production in the pharmaceuticals' sector was Rs 19,737 crore in 1999-2000 (Rs 15,960 crore formulations and Rs 3,777 crore bulk drugs).**
- **Patents (Amendment) Act 2005**
  - **Product and Process patent rights in pharmaceuticals.**
  - **Low share of patented medicines in India**

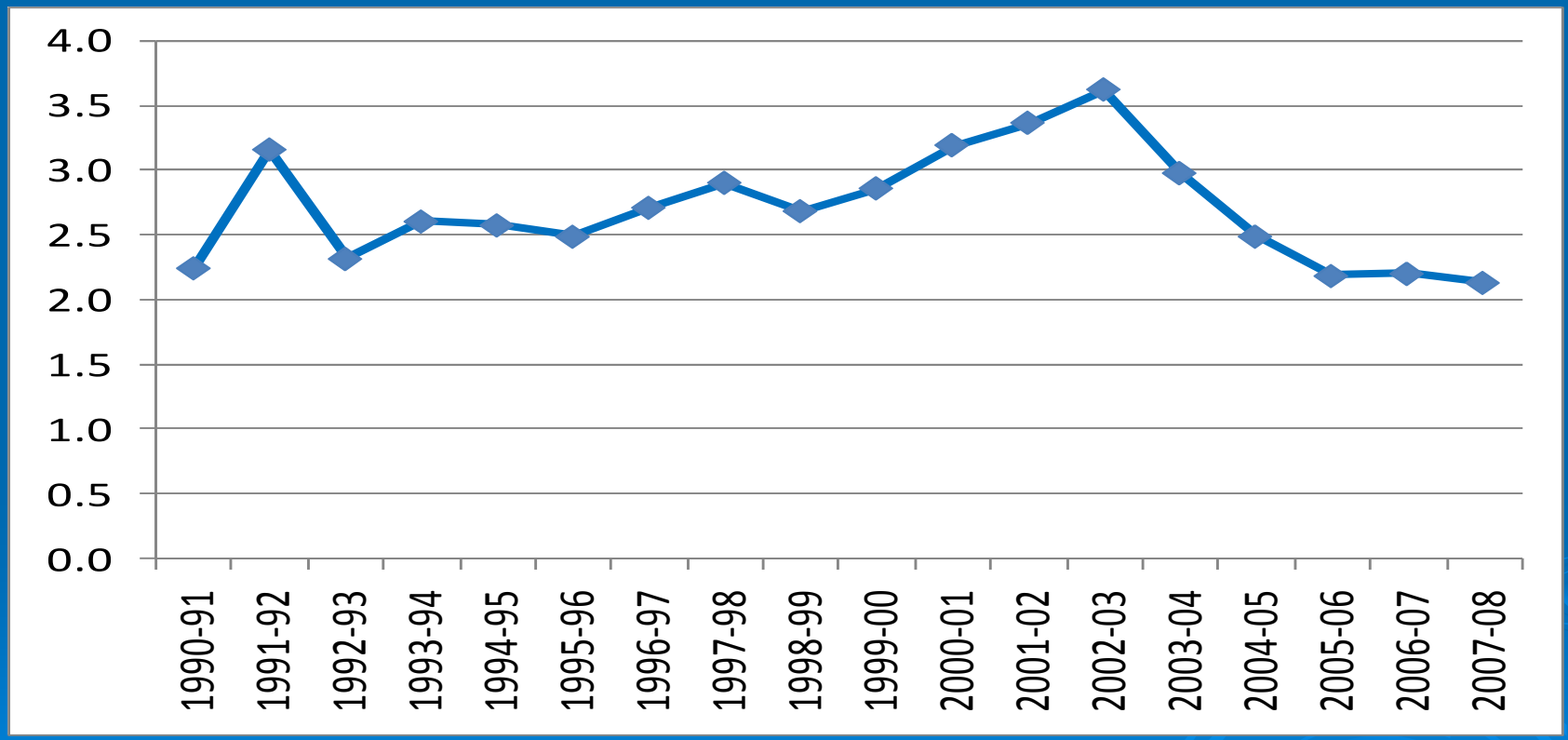
Exports

- **Export promotion has been a major objective**
  - **Examples:**
  - **FERA 1973 exempted 100% export oriented firms**
  - **1986 Drug Policy provided complete flexibility for firms to produce any product with their existing facilities for the export purpose**
  - **More recently firms operating in export processing zones are entitled to customs benefits, tax benefits for export (which could extend up to 15 years) and also capital expenditure benefits**

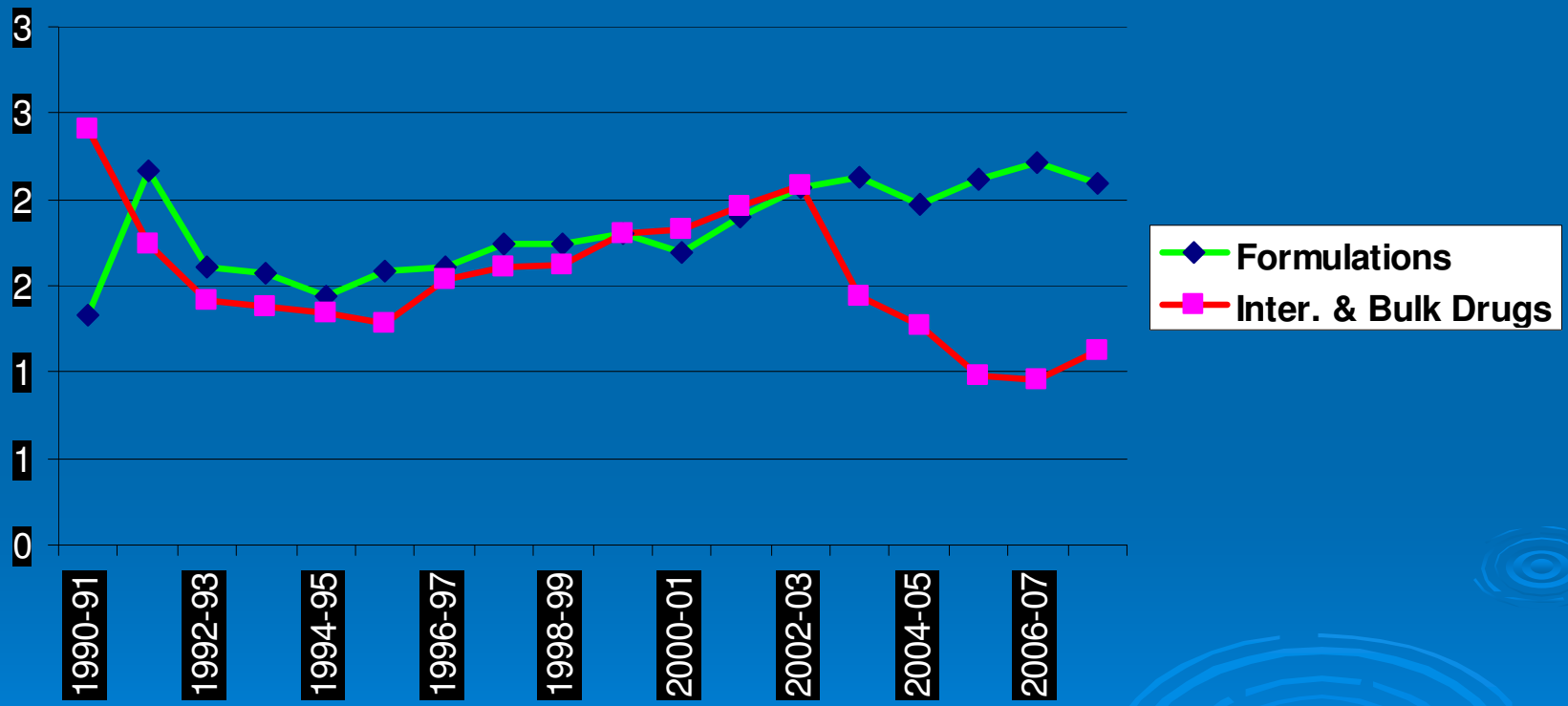
Exports…(US$ Million)

	Formulations	Int.& Bulk Drugs	Others
1990-91	165.9	300.2	16.3
1995-96	494.6	402.0	15 .0
2000-01	754.7	817.9	41.4
2005-06	2185.5	1014.4	50.8
2007-08	3419.3	1827.7	134.6

Share of Pharma in Merchandise exports



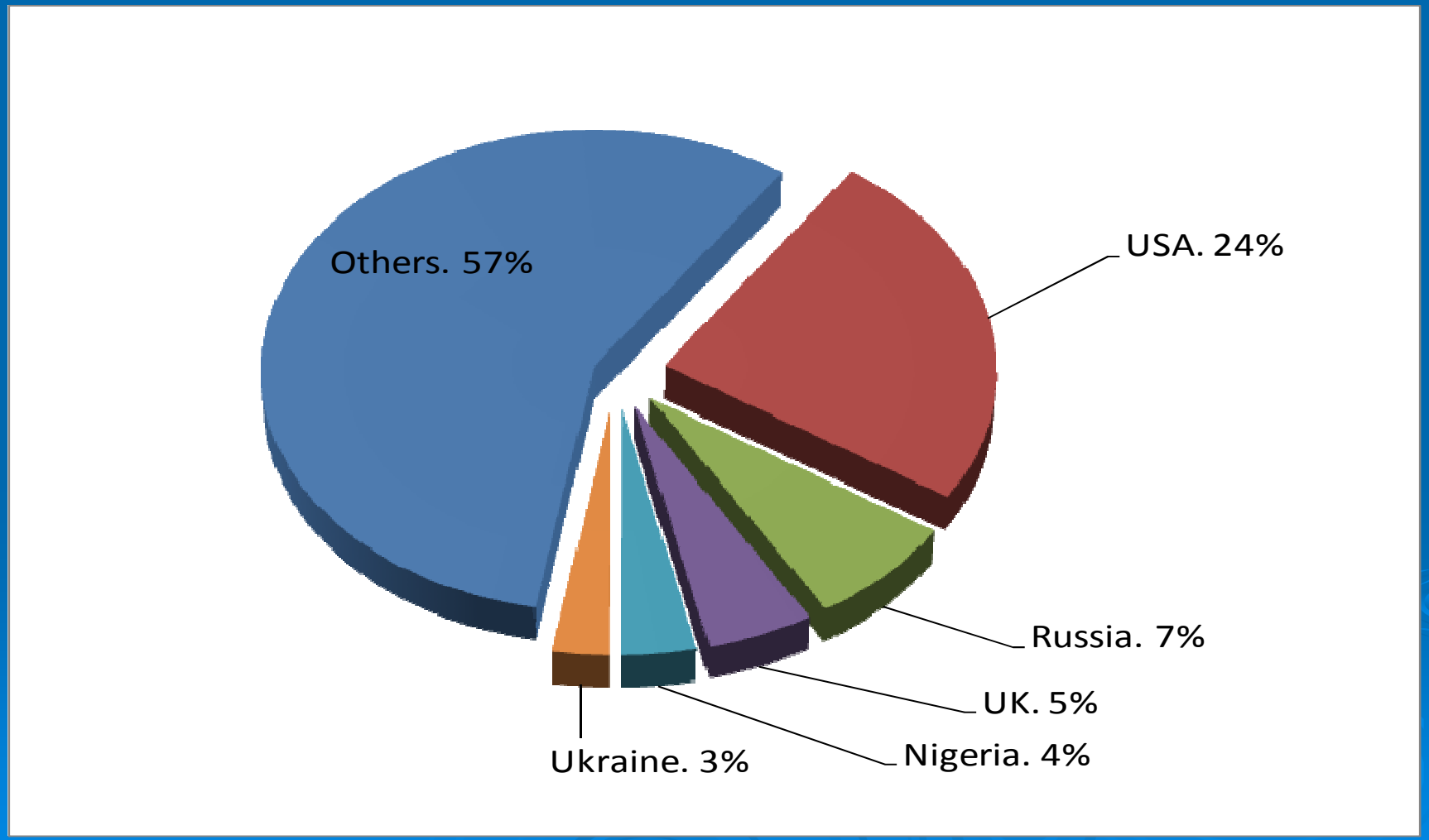
Exports: Share of Formulations and Intermediates & Bulk Drugs in total exports (merchandise)



Exports: Top 10 exporters

	2007-08			2007-08		
	X $ Ml	X%Sale	Share%	X $ Ml	X%Sale	Share%
Dr. Reddy	561.6	63	11	4.6	15	2
Ranbaxy	555.9	69	11	32.2	22	12
Cipla	522.3	49	10	5.3	8	2
Lupin	336.9	51	7	20.7	16	8
Aurobindo	332.9	56	6	0	0	0
Orchid	250.6	81	5	0	0	0
Divi's	239.3	92	5	0	0	0
Sun	200.4	33	4	0	0	0
Glenmark	168.3	48	3	0	0	0
Matrix	152.2	63	3	0	0	0

Exports: Major destinations of formulations in 2007-08



Exports…

- The 'low volume high value' market of USA remains the main attraction for Indian companies.
- India has approximately 119 FDA approved plants; the largest number outside the USA.
- About 250 Indian generics products have been launched in the US market in 2008, as opposed to 93 in 2003
- A company needs to file ANDA (Abbreviated New Drug Application) in order for marketing the drug in USA.
- ANDA approvals held by Indian firms as percentage of total approvals have gone up sharply from 7% in 2001 to 21% in 2006 to 30% in 2008 and to 35% in 2009 till 23rd February.
- 180 days exclusivity if proves that the patent is invalid. This can bring in huge benefits.
  - Dr. Reddy's obtained 180 days exclusivity for "fluxetine 40 mg" in 2001. Company's generic sales increased from Rs 304 million to Rs 4066 million in just one year. "Fluxetine 40 mg" sales contributed 81% of generic sales and half of operating profit in 2001-02 and

Export…

	ANDAs	ANDA-APIs	DMFs
Ranbaxy	251	72	95
Dr. Reddy's	177	49	99
Aurobindo	173	49	126
Wockhardt	116	38	45
Sun	109	34	76
Lupin	81	22	81
Glenmark	63	23	40
Orchid	59	17	24
Cipla	23	9	130
Matrix	20	6	115
Total	1072	319	831

Prices

- **Price control of drugs has been in operation in India since 1963. Drugs (Control of Prices) Order 1963 frozen prices of medicines as on 1st April 1963.**
- **Drug Price Control Order 1970**
  - **18 essential Bulk Drugs and All Formulations were under control. Mark up of 75%.**
  - **100% mark up for formulations which are new combinations of existing drugs**
  - **150% mark up for drugs containing new chemical entities.**
  - **Drawback: No mechanism to check overpricing based on inflated costs.**

Prices…

- **Drug Price Control Order 1979**
  - **Divided drugs into scheduled and non-scheduled categories. Government would fix/revise prices of only scheduled category.**
  - **MRP of scheduled formulations are calculated on the basis of mark ups over material and other costs.**
  - **MRP of scheduled bulk drugs are fixed taking into consideration specified rates of return on net worth/capital employed.**
  - **Divided formulations into 4 categories with separate mark ups.**
    - **Category I (Life saving) - 40%**
    - **Category II (Essential) - 55%**
    - **Category III (Less essential) -100%**
    - **Category IV (Non essential) - no price control**

Prices…

- **Drawback of 1979 DPCO**
  - **It did not have any provision to compel manufactures to produce essential drugs. Focus of production shifted from essential to less essential categories, where the mark ups are higher.**

	Share 1978	Share 1980
Category I	4.5	3.6
Category II	16.7	13.2
Category III	67.1	68.6
Category IV	11.7	14.6

Prices…

- **1986 Drug Price Control Order**
  - **Grouped scheduled drugs into two categories. Group–I consisting of drugs required for the national health program and group – II consisting of drugs other than those in category I but which are also considered essential for the health needs. Mark up of 75% for group-I and 100% for group II.**
  - **scheduled bulk drugs a uniform norm for pricing was adopted based on tax return on net worth/return on capital employed/long term marginal costing.**
  - **Number of drugs under price control came down from 347 to 142.**

Prices…

- **Modifications to "Drug policy 1986" were incorporated later and Drug Price Control Order 1995 was issued.**
- **Criteria for keeping drugs under price control was changed. New criteria is based on "market competition" and "minimum annual turn over".**
  - **A drug with turn over of Rs 4 crore or more, provided the number of bulk drug producers is less than 5 and the number of formulators using the bulk drug is less than 10 and the market leader in retail trade of the formulation has a share of more than 40%.**
  - **A bulk with turnover less than Rs 4 crore but above Rs 1 crore, provided the market leader in the retail formulations market using the bulk drug has a market share of at least 90%.**
  - **Number of drugs under price control came down from 142 to 74.**
  - **Provided uniform mark up of 100% for scheduled formulations.**

Prices…

- **There are checks to on the prices of non-scheduled formulations as well.**
- **Companies will be short listed and will have to provide reasonable explanation if the prices of its nonscheduled formulation increased by more than 10% during a period of 12 months and the annual turnover of the formulation pack exceeded Rs1 crore.**

Prices…

- **Medicine prices in India is one of the cheapest in the world.**

	India	Pakistan	Indonesia	UK	USA
Zantac (Glaxo)	7.16	122.2	658. 4	320.9	739.6
Voveran (Ciba Geigy)	5.6	56.7	177.2	125.8	505.9
Dolonex (Pfizer)	24.7	78.3	218.6	125.9	505.7

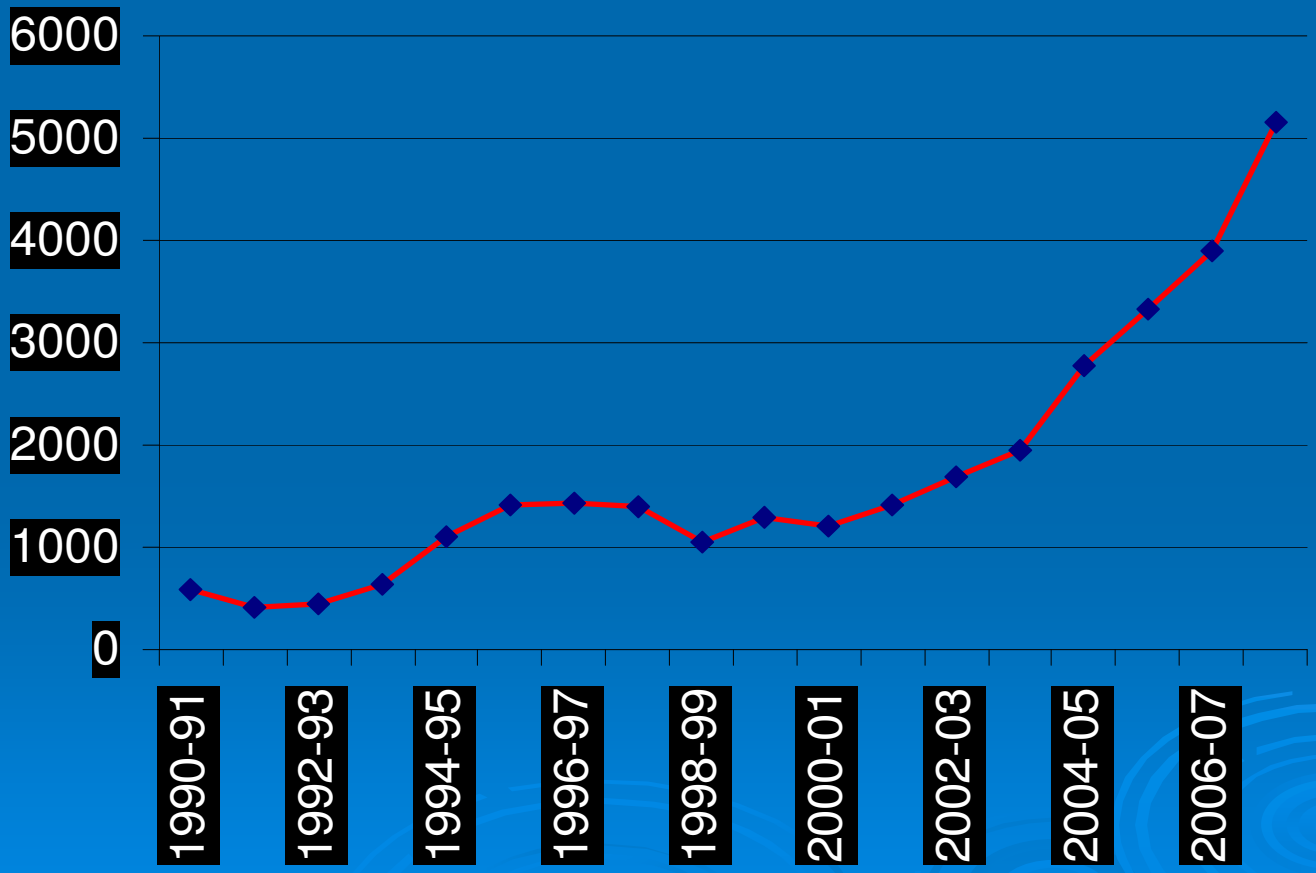
Prices…

- **Price index of medicines**

	1996	2006
Price Index for All Drugs	100	139.93
Drugs Under Price Control	100	100.02
Drugs Outside Price Control	100	237
Drugs in Essential Drug List	100	115

Prospects: Production

- **Increasing dependence on Import of intermediates and bulk drugs**



Prospects: Production…

- **China is the largest source of supply of intermediates and bulk drugs.**
- **15% of the imports are from China in 2007-08.**
- **Report of the Task Force (2008) has pointed out that at times 60-70% of the requirement of intermediates are met by imports from China.**
- **The report points out that the fermentation sector, one of the segments of biotechnology that has been instrumental in shaping Indian antibiotics segment in the early decades of growth of Indian Pharmaceutical industry has moved to China due to lower energy costs there.**

Prospects: Production…

- **The recent crack down of chemical industry in China in order to enforce environmental legislation resulted in shortage of supply and subsequent hike in prices affecting not only the bottom lines of Indian companies but the very existence of many firms. Due to shortage of raw materials and their rising prices, close to 50 bulk drug manufacturing units have been closed down while others have cut down manufacturing of loss making drug categories.**

Prospects: Production…

- **R&D Capability**
  - **Studies have shown that Indian Pharma industry is lacking capability in new innovations. It is competent in process development, but not in product development.**
  - **R&D collaborations with foreign firms**

Prospects: Exports

- **Increasing non-tariff barriers**
  - **USA: Export of bio-generics to US is restricted due to lack of approvals. US allows marketing of only selected biotech medicines.**
  - **Japan: Generic penetration to increase from 17% of now to 30% by 2012.**
    - **Language barrier**
    - **Requirement of partnering with Japanese enterprise/trading houses**
    - **Requirement for keep an inventory for 5 years**

Prospects: Exports…

- **Emerging non-tariff barriers**
  - **Anti-counterfeiting initiatives and IPR enforcement**
  - **Heightened security concerns**
  - **Bilateral FTAs with Trips-Plus provisions**

Prospects: Price

- **Issue of patented medicines**
- **New concepts – Health Impact Fund**

THNAK YOU

Global Politics of Harmonization: Implications for public health

Roger Jeffery

School on Trade and Public Health, New Delhi,
8 October 2009

Regulatory failure in South Asia?

- The general question: why are regulatory efforts in South Asia
  - Partial
  - Detached from local contexts
  - Unable to respond to external contexts

A Local Example: Need for more inspectors …

- Delhi producer: [Regulation] is becoming more and more but still there is lot of scope to do that. … No.1, you have to increase the number of inspectors. That is very important. Delhi, yes because you have limited yourself to a 40 sq miles or may be 100 sq miles area, so you have 40 inspectors. But UP spreads over 1000s of sq miles and you have 40 inspectors. So they really cannot do justice. So number one is that.

But how to regulate the regulators?

- A lot more authority simultaneously becomes a starting point for corruption. So now you have to weigh……. what is more important.
- RJ: OK so more authority, how would you control the authority to prevent corruption? [offered tea] So you don't find drug inspectors misusing their authority?
- AS: In this country anything is possible sir.
- RJ: But in your own experience?
- AS: I would probably like to avoid our interaction directly.
- RJ: So it has happened, would you like to ….
- AS: You can yourself make out you know (*laughs*)

Global example: US FDA and Ranbaxy

- Global: US FDA's concerns about Ranbaxy's compliance with current GMP
  - No evidence of harm to patients
  - Possible cross-contamination of products
  - Employees verify cleaning yet security logs say they were not present at the time
- Protection of US consumers through FDA office in New Delhi (Jan 2009): Indian MNCs highly regulated, but increasingly by foreign agencies more than by Government of India

Two interim conclusions

- At neither end of the local-global continuum is the Indian state an effective regulator
  - Locally, implementation of existing rules is in the hands of over-stretched and untrusted inspectors
  - Globally, standards are continually up-grading
- No real moves to change at the local level, but the FDA (and others) do so at the global level

International Conference on Harmonization: apparently a Good Thing

- In the 1970s, the first schemes were introduced by the WHO and the European Free Trade Association, relying on reciprocal recognition of inspection reports on manufacturer's compliance with the WHO GMP standards.
- In the 1990s, the EU, Japan, and the US harmonised their GMP specifications through the International Conference on Harmonization, creating a second set of international GMP standards

So: is the move to global regulation of pharmaceuticals production desirable?

- To address quality and safety, and ensure the minimum quality of pharmaceutical products, producers must comply with the Good Manufacturing Practice (GMP) standards which govern the production, distribution and supply of a drug.
- GMP is that part of quality assurance “which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by marketing authorization”.
- Quality Assurance is “the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use”

BUT are these standards being manipulated in the interests of some?

- GMP standards are advisory in nature, and alternative processes and control mechanisms can be used if equivalent assurance is attained.
- Typically, the requirements are couched in general terms. No specific requirements are made by regulatory authorities except to prevent things ‘violative’ of the spirit of the guidelines.
  - This enables the manufacturers, giving them creative leeway and freedom in the interpretation of the guidelines.
  - But this also enables regulatory inspectors who could at their worst be arbitrary, whimsical and unscientific following arbitrary dictates of their own.

And beyond India's shores …

- In the global context, how much of these standards, guidelines, and interpretations of specific requirements are based on science, how much on a dominant group's subjective ideas of hygiene, cleanliness, 'civilised' manufacture, etc., is always a matter of conjecture and debate. And naturally the standard setters of this debate, those who call the shots, are those representing the interests of those countries from where big pharma originates. They also represent the dominant paradigms of GMP currently in vogue among the regulatory agencies of these countries

We have been warned

- Timmermans and WHO have warned that if these rules are adopted as global standards, they would negatively impact on generic production in developing countries, because
  - there is no evidence that these stringent standards increase quality
  - adherence to them requires costly upgrade of production facilities, and
  - this would be most problematic for producers in developing countries that operate in the low-margin generics sector.
    - Timmermans K. Harmonization, regulation, and trade: interactions in the pharmaceutical field. *International Journal of Health Services* 2004;34(4):651-61.
    - WHO. International harmonization of regulatory activities: future options. *WHO Drug Information* 2000;14(3):145-59.

In India

- Which groups are in favour of GMP standards being raised? And which are against?
- Government Commissions are dominated by government and industry representatives, with little scope of public health and patient interests
- Some evidence of industry capture but more of ‘modernity capture’: preference for assuming ‘India Shining’ and ignoring ‘Republic of Hunger’ aspects of the local contexts

Conclusion

- In South Asia, attempts to regulate draw too closely on Western experiences despite the very different local contexts
- Pharmaceutical regulation is currently partial and poorly integrated
- A focus on ground-level realities and taking a ‘cradle-to-grave’ approach to the lives of drugs might be a way forward

Conclusions (2)

- Quality standards are essential, BUT
  - There are gaps in knowledge about the outcomes of more stringent good manufacturing standards in terms of quality and price of pharmaceuticals.
  - There are several sets of standards with perceived differences in quality
  - Different interpretation of rules and the particulars of standards can be used as a technical barrier to entry.
  - This turns public health policy issues of quality of pharmaceutical products into an economic and trade issue with important implications for availability and affordability of pharmaceuticals.

Politics of IP Enforcement & Forum Shifting

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Scheme of presentation

- International IP enforcement agenda
- Politics of Forum shifting
  - WHO-IMPACT definition of counterfeits
  - ACTA
  - WCO-SECURE- New initiatives
  - WIPO- New Initiatives

International IP enforcement Agenda

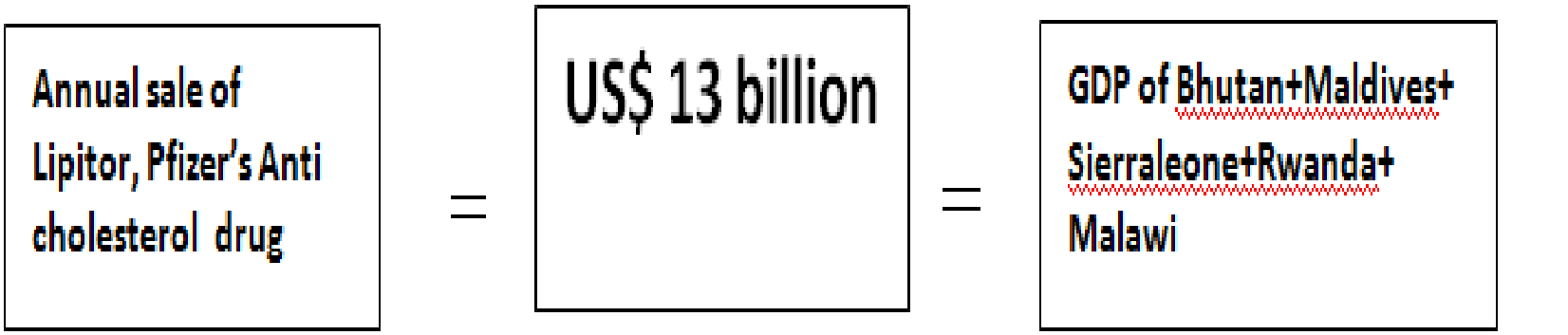
- Efforts to bring in harmonization of standards specifically with regard to IPRs and quality.
- Efforts to conflate the issues of quality and IPR
- Efforts are oriented towards the idea of creating “exclusive rights” and facilitating monopolistic/oligopolistic trade regime
- multilateral organizations are being used by the developed countries to pursue the international IP enforcement Agenda.

What is IP enforcement Agenda

- **Agenda advanced by developed countries under the leadership of US and EU and other OECD countries to strengthen IPR enforcement through various initiatives in different multilateral, regional and bilateral fora.**
- Who all are involved
  - hundreds of OECD based global business firms and their foreign subsidiaries,
    - Pharma, softwares, hollywood
  - IFPMA-
  - Interpol
  - WCO
  - US Chamber of Commerce (USCC)
  - Security and Prosperity Partnership of North America (SPP);
  - WHO's "International Medicinal Products Anti-Counterfeit Taskforce" (IMPACT);
  - WIPO
- Engage in misleading public relations campaign to frighten people
  - Eg -Tales of exploding cell phones, toxic counterfeit drugs, to unsubstantiated allegations of organised crime and even terrorist involvement.

TRIPS is not enough!!

WHY?
Stakes are too high….



Source: IMF and IMS health.

Politics of Forum Shifting

- Forum Shifting: Pushers of IP enforcement agenda shift fora very smartly. As soon as one venue becomes less responsive to a high protectionist agenda, IP protectionists shift to another in search of a more hospitable venue.
- Till late 1970s World Intellectual Property Organisation (WIPO) was the center of IP Negotiations. Then with the Uruguay round negotiations, GATT became the center of IPR negotiations.
- Thereafter WTO-TRIPS
- Frequent deadlocks in WTO negotiations forced G8/OECD countries to engage in aggressive forum shifting

Forum Shifting ..(contnd)

- **Forum shifting** is done basically to optimise the power and minimise the oppositions.
- Usually TRIPS Plus provisions are pushed through newly captured fora.
- New Fora – for pursuing TRIPS plus Agenda are
  - WHO- world health organisation
  - WCO- World Customs organisation
  - FTAs- Free Trade Agreements
  - RTAs- Regional Trade Agreements
  - ACTA- Anti-Counterfeiting Trading Agreement

WHO-IMPACT

- **WHO is the another forum that is captured by the IP maximalists**.
- In 2006, WHO constituted a global coalition of stake holders named **IMPACT** (**International Medical Products Anti-Counterfeiting Taskforce**) to address the issue of counterfeiting of medical products. IMPACT comprises major anti-counterfeiting players, including: international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities.

WHO- IMPACT

- IMPACT **works closely** with several intergovernmental and international organisations such as
  - Interpol,
  - Organisation for Economic Co-operation and Development (OECD),
  - World Customs Organisation (WCO),
  - World Intellectual Property Organisation (WIPO),
  - European Commission and
  - International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

WHO-IMPACT... (contnd)

- What is wrong with IMPACT definition?
- IMPACT unnecessarily combines issues of trademark infringement(IPR), spurious and mislabeled drugs(Quality)
- IPR protection is essentially a protection of private monopoly. Protection of private monopolistic rights is not the mandate of WHO.
- Conflict of interest – IFPMA played an important role in drafting the counterfeit definition
- The WHO dropped its resolution on IMPACT definition due to strong opposition from developing countries including India and Brazil.

ACTA

- **ACTA**- yet another forum for “counterfeits”!!!
- In 2007, under the leadership of US countries such as Japan, Korea, Mexico, New Zealand and EU began a treaty-making process to create a new global standard for intellectual property rights in order **to fight the growing problem of counterfeiting and piracy** , which was called "ACTA" (Anti-Counterfeiting Trade Agreement).
- Secret treaty making
- After two years, a summary of ACTA negotiating document was released a few months back.

Why ACTA is problematic?

- ACTA is expected to
  - Interfere with legitimate parallel trade in goods, including the resale of brand-name pharmaceutical products;
  - Impose liability on manufacturers of active pharmaceutical ingredients (APIs), if those APIs are used to make counterfeits -- a liability system that may make API manufacturers reluctant to sell to legal generic drug makers, and thereby significantly damage the functioning of the legal generic pharmaceutical industry;
  - Improperly criminalize acts not done for commercial purpose and with no public health consequences; and
  - Improperly divert public resources into enforcement of private rights

WCO-SECURE

- **WCO-SECURE**….Forum shifting continues!!!
- World Customs Organisation (WCO) constituted SECURE (Standards Employed by Customs for Uniform Rights Enforcement) Working group in 2007 to lay down global norms and model laws for heightened protection of IP rights.
- IP rights holders enjoy **undue rights** under the provision of SECURE. Eg. rights holders **are not obliged to provide adequate** evidence to show that there is prima facie infringement to initiate action

WCO-SECURE

- The three key activities identified in SECURE were:
  - (I) IPR Legislative and Enforcement Regime Development;
  - (II) Risk Analysis and Intelligence Sharing;
  - (III) Capacity Building for IPR Enforcement and International Co-operation.

WCO- SECURE

- One dangerous Provision in the SECURE was the following :

  "Given the increase in IPR fraud, Customs authorities should extend their control prerogatives beyond goods entering their countries to include goods leaving or transiting their national territory. It is equally important that **Customs authorities be empowered to detain, seize, forfeit and dispose of goods that infringe intellectual property rights.** These Customs prerogatives should be exercised at exportation, at importation, in transit (when health, safety or other risks are concerned), in free zones, and more generally whenever goods are under Customs supervision."

- this imply that more and more so called "counterfeit medicines" (read as generic medicines) will be seized and destroyed without proper judicial enquiry!!!

- Due to severe oppositions from developing countries, global public interest organisations and academia, WCO dropped the idea of SECURE for the time being…
- But Something else in different format is coming up !!!

WIPO initiatives

- Developed countries and MNCs lobby aggressively for the harmonization of major substantive aspects of patent law such as grace period, prior art, novelty and inventive step at the global level.
- Substantive Patent Law Treaty (SPLT) proposed by the WIPO is meant to address the issues and concerns raised by these so called “IP inventors”.
- To speed up the harmonization process efforts have already begun in WIPO.

WIPO

- Efforts have begun to introduce new global IP infrastructure - to harmonize the patent administration.
- Planning to dismantle the Standing Committee on Information Technologies (SCIT).
- SCIT will soon be replaced by Committee on WIPO Standards (CWS), and a Committee on Global IP Infrastructure (CGI).

THANK YOU

Current and Proposed Domestic Laws & Policies on Public Health (Special emphasis on: Draft Health Bill Government of India)

SHRUTI PANDEY, ADVOCATE
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International legal understanding of health

Legally “health” is understood as inclusive of “public health”

Internationally, it was first articulated in the 1946 Constitution of WHO, whose preamble defines health as:

“a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.

- Alma Ata also reduced the gap between health and public health

ICESCR, Article 12 on right to health

- Art 12.1 of ICESCR recognizes right to "the highest attainable standard of physical and mental health" - not confined to right to health care

- Drafting history and express words of Art 12.2 acknowledge that right to health embraces a wide **range of socio-economic factors that promote conditions in which people can lead a healthy life**, and extends to the **underlying determinants of health**, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.

Contents of right to health in ICESCR

- Art. 12.2 (a): Right to maternal, child and reproductive health: “provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child”
- Art. 12.2 (b): Right to healthy natural and workplace environments : "improvement of all aspects of environmental and industrial hygiene“
- Art. 12.2 (c): Right to prevention, treatment and control of diseases: "prevention, treatment and control of epidemic, endemic, occupational and other diseases"

Contents of right to health in ICESCR-contd.

- Art.12.2 (d): Right to health facilities, goods and services: "creation of conditions which would assure to all medical service and medical attention in the event of sickness", both physical and mental, **includes the provision of equal and timely access to basic preventive, curative, rehabilitative health services and health education; regular screening programmes; appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at community level**; the provision of essential drugs; and appropriate mental health treatment and care.

Contents of right to health in ICESCR-contd.

- Non-discrimination and equal treatment:

  Under Arts. 2 & 3, ICESCR bans any discrimination in access to health care and underlying determinants of health, as well as to means and entitlements for their procurement, on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation and civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health.

Right to Health - contd.

"The right to the highest attainable standard of health in international human rights law is a ***claim to a set of social arrangements*** - ***norms, institutions, laws, an enabling environment*** - that can best secure the enjoyment of this right."

(World Health Organization, 2002: 25 Questions and answers on health and human rights)

ICESCR - Entitlements versus Freedoms

- The right to health contains both freedoms and entitlements.
- The entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.
- The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation.

Limits of individuals' rights

- The tension between the two is recognised in Art. 4 - Right to health, like other economic, social and cultural rights is subject to limits determined by law for promotion of general welfare in a democratic society.
- In cases where restrictions on rights are necessary, the Committee on ESRs has emphasised that such restrictions must be:
- "in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interests of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society".

Nature of restrictions on individuals' rights:

- Committee on Economic, Social and Cultural Rights has emphasised that the restrictions must be "primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by states".

- Therefore, such limitations: "must be proportional, i.e. the *least restrictive alternative* must be adopted where several types of limitations are available. Even where such limitations on grounds of protecting public health are basically permitted, they should be of limited duration and subject to review".

Prevention, treatment and control of diseases

- For prevention, treatment and control of diseases the Committee states that it “requires the establishment of prevention and education programmes for behaviour-related health concerns such as sexually transmitted diseases, in particular HIV/AIDS, and those adversely affecting sexual and reproductive health, and the promotion of social determinants of good health, such as environmental safety, education, economic development and gender equity. ...(contd.)

Prevention, treatment and control of diseases – contd.

"The right to treatment includes the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards, and the provision of disaster relief and humanitarian assistance in emergency situations.

The control of diseases refers to States' individual and joint efforts to, *inter alia*, make available relevant technologies, using and improving epidemiological surveillance and data collection on a disaggregated basis, the implementation or enhancement of immunisation programmes and other strategies of infectious disease control."

Right to Health - an inclusive right

- "The Committee interprets the right to health as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health."

- "A further important aspect is the participation of the population in all health-related decision-making at the community, national and international levels."

Indian Constitutional provisions regarding Health/ Public Health

Title III (Fundamental Rights):

- Art 14: Equality before law
- Art. 21: Protection of life and personal liberty – judicially (SC & HC) right to life seen to include determinants of life including health, food, water, clean environment, shelter
- Others - Art.15: Prohibition of discrimination on grounds of religion, caste, sex or place of birth; Art. 17: Abolition of untouchability; Art. 23. Prohibition of traffic in human beings, forced labour; Art. 24: Prohibition of employment of children in factories etc.

Indian Constitutional provisions re Public Health (contd.)

Part IV (Directive principles of State policy):

- Art. 41: Right to work, to education and to public assistance in certain cases
- Art. 42: Provision for just and humane conditions of work and maternity relief
- Art.47: Duty of the State to raise the level of nutrition and the standard of living and to improve public health
- Art. 48A: Protection and improvement of environment

India's international commitments to health rights:

- Article 25(1), Declaration of Human Rights (UDHR)
- Article 12, International Covenant on Economic, Social & Cultural Rights (ICESCR)
- Article 24,Convention on the Rights of the Child (CRC)
- Article 12, Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)
- Article 25, UN Convention on Rights of Persons with Disabilities (UNCRPD)

Central Govt is empowered, under Art 253 of Constitution, to legislate to enforce international commitments it is signatory to (+Schedule VII, List 1)

Such health laws have been introduced by many other countries – notably South Africa, Canada, UK, Argentina, Australia

Indian Supreme Court's Rulings:

- Numerous judgments of Supreme Court and High Courts – viewing right to health as integral part of right to life, *along with* food, water, housing, sanitation, clean environment, right to pollution free water and air, education, livelihood

  In Municipal Council, Ratlam vs. Vardhichand & Ors (1980), while rejecting the plea of monetary constraints for performing its duty of cleaning up the garbage, advanced by the municipal corporation, Supreme Court also relied upon Article 47 which the court said makes it a paramount principle of governance that steps are taken for the ***improvement of public health as amongst its primary duties***.

Centre- State division of powers on health

- Indian Constitution enumerates the separate and shared legislative powers of Parliament and State Legislatures in three separate lists in Schedule VII: Union List, State List and Concurrent List.
- The Parliament & State legislatures share authority over health matters on Concurrent List: health related economic & social planning; population stabilization & family planning; mental health; drugs; food safety; labour safety and welfare, including maternity benefits; prevention & control of communicable diseases or vectors affecting humans; registration of births and deaths and other vital statistics for health; social security and social insurance; medical professions.

Centre-State domains – contd.

- On matters in Union List, the Parliament of course has total supremacy: matters like entering into and implementing all international treaties and agreements & some specifically health related matters like port quarantine; seamen's and marine hospitals; regulation of labour & safety in mines/ oilfields.
- The Parliament generally has no power to legislate on items on State List, like: public health, hospitals & dispensaries, water and sanitation. However, two-thirds of Rajya Sabha may vote to allow parliament to pass binding legislation on any state issue if "necessary or expedient in national interest". Or, 2 or more States may ask Parliament to legislate on a State subject.

GoI or State public health legislations in India

- GoI's Public Health Ordinance of 1944

- GoI's draft public health bills – 1955, 1987, 2002 (the last one by NICD): all are 'model' public health Acts, for the States to adopt

- Many States have public health laws: Tamil Nadu (1939), Pondicherry (1973): have detailed provisions on water supply, prevention & control of communicable diseases, waste disposal, housing & food sanitation, nuisances, fairs/ festivals, places of pilgrimages, resorts, settlements & labour camps, burial/ burning grounds, licensing, regulation powers and functions of state health authorities. But - largely poorly implemented, focus poorly on health care services, poor in rights framework

- Draft PH Bills in: Gujarat, Karnataka, Kerala – comparatively much more progressive; still in the process of drafting

Public Health related National Policies/ Programmes

- National Drugs Policy, 1986: to ensure abundant availability & affordability of essential life saving & prophylactic medicines; strengthening quality control of drug production & promoting rational use of drugs
- National Population Policy (NPP), 2000
- National Health Policy (NHP), 2002

  Main common concerns of public health in NPP & NHP: prevention & control of communicable diseases; containment of HIV/AIDS infection; universal immunization of children for major preventable diseases; addressing unmet needs for basic repro health services, supplementation of infrastructure.
- National Rural Health Mission (2005-12), draft NUHM

Other health related legislations in India

- On specific health issues like: drugs; food safety; medical education, licensing; mental health; smoking/tobacco; sex selection; MTP; organs transplant; registration of births, deaths; maternity benefit; occupational hazards; environment; disabilities; motor accidents

- Some pending health related bills: HIV/ AIDS bill, Clinical Establishments Regulation bill etc.

- Some other bills that are indirectly related to health

Draft National Health Bill, 2009:

- Eventhough not a public health law, being a framework law, which sets down the broad principles, norms, rights, obligations and institutional structures/ mechanism on all areas of health, it also covers public health

- This would also ensure that public health is viewed within a rights framework and ensures a balance of individual and community rights on health

The proposed Health Act of GoI would be:

- An overarching, '*framework'* law laying down health obligations & rights including but not limited to 'health care'/ users' rights; and broader principles, norms & structures – the relevant & necessary rules, regulations, standards to flow from this
- Leaves room for, enables, guides and obligates the States to enact their own public health laws, to perform what are traditionally seen as 'public health' functions, including sanitation and water supply, within rights based framework – implementing and subsidiary legislation – the Bill ensures their uniformity and coherence
- All the health related laws/ bills – central & state, current, pending & future – to be tested against this touchstone
- Lays down appropriate structural mechanisms for actualizing public health rights – implementation, monitoring and redressal - with community involvement and participation

Govts' obligations: general, progressive; and core

- **General obligations , towards progressive realization:** Appropriate budgetary allocation & equitable distribution of resources; Underlying determinants apart from health care; Free & universal health care; Least restrictive limitations, in public interest; Health & equity impact assessment; Convergence; Compliant bilateral/ international agreements

- **Core obligations** – immediate, non-derogable and non-negotiable – minimum & essential levels of food, water, sanitation, housing, review of policies, strategies and plans of action in all areas – as (these are 'core' areas as per the UN mandate)

Governments' obligations – contd. central, state and concurrent levels

- Obligations to provide health care services: ensure users' rights; lay down all necessary standards and norms; set up HIS; training health personnel; ensure women's and children's comprehensive health; preventive measures; address public health emergencies

- Specific public health obligations of central government and of state governments - as per constitutional division of domains

Rights in relation to health

- Right to health – standard of physical & mental health conducive to living a life in dignity
- Right to access, use & enjoy – health care and underlying determinants (food, water, sanitation, housing)

  Right to underlying determinants defined as per the international standards – assurance of *minimum & essential*, linked with *'affordability'* that has been defined as through direct govt provisioning, or subsidization, or financing, or other appropriate social security mechanism – especially for those unable to meet their basic needs by their own means for reasons beyond their control (age, disability, natural disaster, social or eco vulnerability

Individual and collective rights in relation to health – contd.

- Right against discrimination (re access or means & entitlements to access, use, or enjoyment) – includes affirmative action
- Right to dignity – respect, tolerance and humanness; no coercive health measures or indiscriminate denials
- Right of participation (in decision making, action); right to information (on all health related info, including on health impact assessment, resource allocation)
- Right to justice – grievance redressal mechanism
- Rights related to health care – Users' rights (details in next slide)

Rights specifically related to healthcare (Users' Rights):

- Right to survival, security and integrity
- Right to seek healthcare and treatment
- Right to receive, use and enjoy healthcare
- Absolute right to emergency treatment and care
- Right to quality of care, rational health care
- Right to continuity of care; Referral rights
- Right to information; Right to medical records
- Autonomy/ self-determination and prior voluntary informed consent
- Confidentiality, information disclosure, privacy
- Reproductive and sexual health care

Implementation Mechanism:

- Public health boards at national and state levels:

- National Public Health Board

- State Public Health Boards

These boards would provide direction for policies and strategies, in compliance with this law,

The boards would also be apex 'regulatory' bodies – ensuring laying down of standards and protocols

The Boards would also ensure coordination and convergence

- Time frame for District, Block and Village level planning and implementation authorities

Monitoring mechanism –

- Robust community involvement
- Concurrent monitoring to the maximum possible extent
- Based on detailed quality assurance system with specific monitorable indicators and benchmarks;
- Linked on an ongoing basis to corrective decision making bodies
- Health Information System
- Monitoring by or on behalf of Governments –

Financial audits; Audits of medical records; Audits into maternal and infant deaths and deaths in unusual circumstances; monitoring for performance benchmarks

- Community based monitoring – PRI involvement

Redressal Mechanism for Health Rights:

- Judicial remedies as last resort, facilitating citizens' access to them: dedicated and especially trained/ sensitised health court in each district (designated from amongst the existing district courts)
- Empowered community bodies with PRI to set first level of dispute resolution on health rights
- Grievance redressal through In-house Complaints Forums at institutional level
- Cause of action for complaints; reliefs, remedies; some special enforcement provisions

Public health provisions of draft NHB

Definitions:

- "health care" means testing, treatment, care, procedures and any other service or intervention towards a therapeutic, nursing, rehabilitative, palliative, convalescent, preventative, diagnostic, research and/or other health related purpose or combinations thereof, including reproductive health care and emergency medical treatment, in any system of medicine, and also includes any of these as a result of participation in a medical research programme;

- “Health Impact Assessment”: A combination of procedures, methods and tools for identifying, predicting, evaluating and mitigating potential effects of proposed a law, policy, programme, project, technology or a potentially damaging activity, in relation to health, prior to taking decisions thereon and making commitments thereunder, on the health of the population, and other relevant effects, and the distribution of those effects within the population, any reference to “HIA” shall mean the same;

- m) “Health Information Systems” means systems, technical and institutional, for collection, processing, analysis, dissemination and utilization of data and information related to health of individuals and populations, and any reference to “HIS” shall mean the same;

- t) “indicator” means a numeric measure that depicts the status of a population or a health system on a core health care or public health construct;

- “least restrictive alternative” means a modified policy, practice or intervention adopted by or on behalf of the Government for the purpose of meeting certain exigencies or legitimate goals of public health or health of community, that directly or indirectly restricts an individual’s health rights only to the extent demonstrably justified by objective standards to meet such exigencies or goals, and among the possible alternatives, the one that does so to the least extent;

- “public health emergency” means an unusual or unexpected occurrence or imminent threat of illness or health condition that requires immediate intervention in the interest of public health to prevent, mitigate or otherwise address large number of deaths, illness, serious or long term disabilities, in the affected population, including teratogenic effects, or widespread exposure to any infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population;

3. General obligations towards progressive realization of health and well-being: Government of India and the State Governments have the following general obligations at all times, within the maximum limits of their available resources, towards the progressive realization of health and well being of every person in the country….(b) Take all measures and steps, for addressing bio-medical determinants as well as the underlying socio-economic, cultural and environmental determinants of health and wellbeing to ensure the enjoyment of right to health and well-being of every person, equally and without any discrimination;

(d) Ensure comprehensive involvement of civil society, especially vulnerable or marginalized individuals/ groups, including by enabling them to effectively articulate their health needs and to participate in all health related decision-making processes, including in setting health priorities and goals; and in devising, planning, implementing and evaluating the policies and strategies for health and well-being at every level; also integrally incorporating their roles and participation in the contents of such policies, strategies and plans; and ensuring demonstrably serious consideration to diverse expert views, in the planning of health care;

(e) Where imposition of limitations on right to health of individuals becomes necessary in compelling public health or interest, ensure proportionality of such limitations by adopting the least restrictive alternative, and in any case ensure that they be of limited duration and subject to review against the reference to the rights provided for herein;

6. Specific public health obligations: (1) Obligations of Central Government3: The Government of India shall take appropriate legal steps, including where necessary, enactment of laws, or review/ amendment of existing public health related laws, and/or strict implementation of laws, but in any case, through its powers to issue rules/ regulations/ orders/ bye-laws under this Act, to specifically address the following and/ or any other area that it is competent to legislate upon under the Constitution of India:

- a) Prevention and control of communicable diseases;
- b) Public health emergencies of international concern;
- c) Registration of births and deaths and other vital statistics for health;
- d) Food safety;

- e) Safety, availability and accessibility of drugs; rational use of drugs and monitoring of microbial resistance;
- f) Labour safety and welfare, including maternity benefits;
- g) Port quarantine, seamen's and marine hospitals;
- h) Health related aspects of social security and employment;
- i) Population stabilization and family planning;
- j) Special public health measures for certain vulnerable or marginalized sections of
- population; All the other health related social and economic planning; and
- k) Coordination of public health policies and actions at the State levels

- (2) Obligations of State Governments: The State Governments shall take appropriate legal steps, including where necessary, enactment of laws, or review/ amendment of existing public health related laws, and/or strict implementation of laws, but in any case, through their powers to issue rules/ regulations/ orders/ bye-laws under this Act, to address the following and/ or any other area that they are competent to legislate upon under the Constitution of India, for their respective States:
- a) Disease outbreaks;
- b) Public health emergencies;
- c) Health establishments and all the facilities providing health services;
- d) Health nuisances and bio-medical waste;

- e) Availability and accessibility of safe drinking water;
- f) Sanitation and environmental hygiene, including waste management for every of waste;
- g) Hygiene and safety in places and situations of public health importance including fairs, festivals, cinema, theatres, circuses, markets, shopping places, malls, lodging houses, burial and burning grounds, slaughter houses;
- h) Environmental disasters, environmental safety,
- i) Occupational safety and industrial hygiene;
- j) Health Impact Assessment (HIA) of all new development projects;
- k) Protection from and abatement of hazardous and injurious substances and activities or any other health hazards;

- Lifestyle related diseases; mental illnesses, widely prevalent diseases; public health related factors like use of tobacco, alcoholism and other substance abuse, and consumption of unhealthy foods; and promotion of healthy lifestyles like breast feeding, health seeking behaviour, balanced diet, regular exercising, food and water safety, including with regard to their packaging, labeling, advertising and sale and consumer protection, including regulating advertising and taxation and excise polices that have impact on these;
- m) Road and transport safety, accident injuries/ trauma care;

n) Special public health measures for vulnerable or marginalized individuals and groups of population; and

o) Any other public health measures towards ensuring health and well being of all, including physical, emotional and mental health.

Expected roles of legal framework

- Four possible roles that the law would play:
  1. Prescriptive role – mandating/ enabling certain actions by certain actors towards health of people
  2. Proscriptive role – outlawing and banning certain actions/ non-actions impinging on people's health
  3. Protective role – recognizing and supporting people's health rights & interests – concomitant obligations of state to "*respect*, *protect* and *fulfill*"
  4. Instrumental role: changing mindsets, behaviours, systems, society to promote health/prevent disease

Thank you

Tobacco Control Law -
A public health rights perspective

Exercise Question: What do you think are the public health rights concerns towards tobacco control/ smoking cessation, which must be included in a law for addressing it?

What is right to health?

- ***"The right to health is not to be understood as a right to be healthy. …There are a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health.*** *Thus, genetic factors, individual susceptibility to ill health and the* ***adoption of unhealthy or risky lifestyles*** *may play an important role with respect to an individual's health. Consequently,* ***the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."***

  (Committee on Economic, Social And Cultural Rights (ESCR Committee), General Comment No. 14 (2000), paras 8 & 9)

What is right to health – contd.

"The right to the highest attainable standard of health in international human rights law is a ***claim to a set of social arrangements - norms, institutions, laws, an enabling environment*** *- that can best secure the enjoyment of this right."*

(World Health Organization, 2002: 25 Questions and answers on health and human rights)

Right to Health Care

'Health care' includes the entire range of ***preventive, promotive, curative and rehabilitation services***, mainly bio-medical, which are carried out with the primary objective of ***maintaining or restoring health***, *including health infrastructure, health human resource/ manpower, drugs and equipment, and all the other facilities for addressing ill-health and diseases*. These services are largely provided by the health care system, which includes both the public health system and private health care providers.

What then is the meaning of right to health re tobacco use?: Public health rights re tobacco use - 1

Health consequences:

- Adverse health impacts (morbidity and mortality) caused by tobacco use:
  - ***on individuals***
  - ***on special vulnerable groups,*** like – children, women, pregnant women, workers in tobacco farms and manufacturing companies, the consumers, the poor

- Mainstreaming of tobacco control interventions in the public health related interventions

Public health rights re tobacco use – contd. 2

Public health dimensions of tobacco control: impact on individual versus impact on public

- Tobacco related health and socio-economic issues for those around the smoker are at least as important as the problems for the smoker himself or herself.

- We know that many tobacco-related problems endanger or harm not just the person who smokes but also others: the unborn child, the smoker's family, friends and work colleagues, and the community as a whole.

These negative effects on people other than the smoker are additional very strong arguments for concerted action towards tobacco control. Therefore there is a very strong case for -

- ***preventive interventions and***

- promotive interventions (health promotive!)

Public health rights re tobacco use – contd. 3

Health Economics of Tobacco Control:

- ***health care costs*** – on individuals, families, communities/ country and governments, in dealing with the adverse health impacts of tobacco use; also impact on the access to other health care; also impact on the access to other basic needs

- ***Disability-Adjusted Life Year (DALY = YLL + YLD)*****:** measure to quantify the impact of premature death (YLL – Years of Life Lost) and disability (YLD - Years Lived with Disability) on a population - both time lost due to premature death and time spent disabled by disease caused by tobacco use

Public Health rights re tobacco use – contd. 4

Curative health care:

- Smoking cessation
- Treatment of tobacco related diseases
- Rehabilitation
- Special health care for affected children, women, workers

Public Health rights re tobacco use – contd. 5

Human Rights (of individual & collectively):

- ✓ Right to equality, equity and development
- ✓ Right to food
- ✓ Right to education
- ✓ Right to information; Right to decide/ self-determination/ autonomy
- ✓ Right to occupational safety,
- ✓ Right to environment
- ✓ Right to benefits of scientific progress
- ✓ Right against coercion or right not to be forced – free informed consent
- ✓ Right to justice

Public health rights re tobacco use – contd. 6

Accountability-Liabilities of:

- Tobacco companies, tobacco growers
- Governments and public bodies
- Individuals - smokers
- Other important stakeholders like: health service providers, media, advertising companies, employers, public health researchers, communities

Enforcement and Justice mechanism:

The interplay of legal mechanisms around all the aforementioned areas and issues have to be examined and understood - laws, their enforcement & justice system

India's "Cigarettes & other Tobacco Products (Prohibition of Advertisement & Regulation of Trade & Commerce, Production, Supply & Distribution) Act, 2003"

This is a criminal law that holds penal sanction (punishments) for committing certain illegal acts (offences).

Salient features:

- Prohibits smoking in public places
- Prohibits advertisement of tobacco products
- Prohibits promotion of tobacco use
- Prohibits sale of tobacco products to children (persons below 18 years of age)
- Regulates production, supply, distribution, and trade & commerce – labeling, health warning,

But leaves several important issues, even trade and commerce related, untouched:

- Taxation
- Smuggling
- Lifestyle advertising or any indirect advertising
- Obligations of state for information, education and communication, cure and rehab

Thank you!

Protection of Traditional Knowledge

Sudhir Krishnaswamy

Outline of the Presentation

- Traditional Knowledge and Culture
- Interface between TK and IPR
- Offensive Approaches
- Defensive Approaches
- Sui Generis Regimes
- International Regulatory Framework

Traditional Knowledge and Culture

- Traditional - Age and Pedigree
- Informality – Form and Circulation
- Subject Matter – Wide Coverage
- Scope of Protection – against misappropriation or property right
- Duration – fixed terms or in perpetuity

Interface between TK and IPR

- Misappropriation and Biopiracy
  - Who claims
  - Group vs Individual right
  - Satisfying Formal procedures
- Cultural Norms of Knowledge Regulation
  - Sacred and Religious Knowledge
  - Secret Knowledge
  - Norms on Circulation

Offensive Approaches

- Use existing IPR mechanisms to protect IPR
  - Develop TK to fit the requirements of IPR
  - Modify IPR to allow protection of TK

- Institutional efforts
  - CSIR
  - NIF

Defensive Approaches

- Patent Law Reform
  - Disclosure
  - Subject matter Exclusion
- Archiving
  - State, Institutional and Community Archives
  - Databases and Registers
  - Weak interface between IPR and Databases

Sui Generis Approach

- General TK Law
  - Defining Traditional Knowledge – Subject Matter
  - Creating Property Right
  - Scope and Duration
- Multiple Legislative Initiatives
  - Biodiversity Law – Disclosure, PIC and ABS
  - GI Law
  - Patent Law
  - Plant Varieties Law

International Regulatory Framework

- WIPO Inter-Governmental Committee
  - 14 Meetings – returned to GA for a new mandate
  - Difficulties in definition – 5th Meeting
  - Very little progress in developing draft treaty
- UNESCO
  - Convention on Cultural Diversity
    - National Ownership
- CBD
  - Biodiversity and Associated Knowledge
  - National Ownership

Global Institutions and Responses to Public Health

In Context of IPRs

Ujjwal Kumar

9 October 2009, New Delhi

Post Doha the general direction of IP negotiations at global forums can be summed:

Developed countries, in general, tend to reduce flexibilities in TRIPS, while developing countries, in general, want not only to retain these flexibilities, but further inculcate development dimensions into the process and content of negotiations.

Global Institutions

- WTO
  - TRIPS
  - Doha Declaration and TRIPS&PH
- WHO
  - GSPOA
  - IMPACT
- WIPO
  - Patent Agenda
  - Development Agenda
- Others

WTO

- TRIPS Flexibilities
- Doha Declaration
- Proposed Art. 31*bis* in TRIPS
- Counterfeit drugs & EC seizure (detaining)

WHO - GSPOA

- 56th World Health Assembly, May 2003
  - Showed concern - Insufficient fund in R&D of neglected diseases
  - Noted - Pharmaceutical sector must address public health needs and not only potential market gains.
  - Requested DG-WHO to establish TOR for a time-limited body to analyze IP and other incentives and funding mechanisms for R&D for neglected diseases and proposals for actions.
- CIPIH was established in February 2004

WHO – GSPOA…

- April 2006 – CIPIH Report submitted containing 60 recommendations
- Considered by 59th WHA, May 2006
  - Establishes IGWG
    - To draw (1) Global Strategy and (2) Plan of Action in order to provide a medium-term framework based on CIPIH recommendations
    - Aim – securing sustainable basis for needs-driven essential health R&D for neglected diseases
    - Particular attention to areas of early implementation
    - To report its progress to 60th WHA in May 2007
    - To submit final report to 61st WHA in May 2008

WHO – GSPOA…
1st IGWG

- Importance of management of IP (and transfer of technology) emphasized and included; two dimensions:
  - Incentive to innovate
  - Access to medicines
- Some delegates felt IP management did not fall within WHO's ambit, while others felt the opposite
- Areas of early implementation (low hanging fruits)
- Suggestions came for alternative ways of promoting R&D
  - Prize Fund
  - R&D Treaty

WHO – GSPOA…
60th WHA

- Noted Areas of early implementation carved out from the CIPIH recommendations.
- Resolution on IP (WHA60.30) adopted
  - Moved by Brazil
  - US disassociated itself from decision
- Requested WHO to provide technical and policy support (in collaboration with other competent international organisations) to countries that intend to make use of TRIPS flexibilities for promoting access to drugs.
- Encouraged the development of proposals for health-needs driven R&D for discussion at IGWG (also to address linkage of cost of R&D and price of medicines)

WHO – GSPOA…
2nd IGWG, IGWG 2bis, 61st & 62nd WHA

- 2nd IGWG, 5-9 November, 2007
  - A/PHI/IGWG/2/2 dated 31st July 2007
  - Rio Text
  - Written submissions from countries / regions
  - Amalgamated text released
  - Outcome: A/PHI/IGWG/2/Conf. Paper No.1 Rev.1 - 125 texts, either undecided or un-discussed
- IGWG 2*bis,* 28 Apr – 03 May, 2008
  - only 18 texts were left undecided
- 61st WHA, 19-24 May 2008
  - Special drafting group – Global strategy portion a clean text, some 10 square brackets related with "stakeholder" in plan of action portion
  - Resolution WHA61.21 – Expert Group on R&D financing; and Quick Start Programme
- 62nd WHA, May 2009 – POA agreed

WHO – GSPOA…

- US and some other developed countries wanted to reduce TRIPS Flexibilities (e.g. "…TRIPS flexibilities recognised under Doha Declaration…") However could not succeed
- GSPOA, para 18: "Intellectual property rights do not and should not prevent Member States from taking measures to protect public health"
- Deletion of text on counterfeit drugs
- Although GSPOA is not a binding instrument, if implemented in its spirit it can be very useful ; political will required

WIPO – Patent Agenda

- Patent Law Treaty (PLT)
  - harmonizes the procedures for applying for, obtaining and maintaining patents
- Patent Cooperation Treaty (PCT)
  - Amendment to PCT to simplify and streamline procedure for international filing, and also aligning it with new PLT standards (international searches and international preliminary examination, and time limits for entering the national phase)
  - Major concern of the agenda on PCT reform is that it can skip “patent application examination” process of a country (countries may have different standards of patentability criteria)

WIPO Patent Agenda

- SPLT
  - aimed at creating uniform substantive patent law standards on issues such as prior art, novelty, utility and inventive step, disclosure, drafting and interpretation of claims, grounds for refusal of an application, and issues relating to revocation and invalidation of patents
- No progress since long due to opposition from developing countries

WIPO Development Agenda

- 2004, Argentina & Brazil, proposal to establish development agenda for WIPO
- the proposal notes that various norm-setting activities that are on-going in WIPO must take into account the importance of public interest flexibilities
- Progress made – an agenda adopted (45 recommendations) by WIPO Assembly in 2007
- At present, demand to provide resources for implementing DA and to form a mechanism for coordination, assessing and monitoring the implementation of DA