ARAB REPUBLIC OF EGYPT
MINISTRY OF FOREIGN AFFAIRS

ACADEMY OF SCIENTIFIC
RESEARCH AND TECHNOLOGY

WIPO
WORLD **INTELLECTUAL PROPERTY** ORGANISATION

Second WIPO Inter-Regional Meeting on South-South Cooperation on Patents, Trademarks, Geographical Indications, Industrial Designs and Enforcement

Formulation and Implementation of Intellectual Property (IP) Strategies and WIPO's Development Agenda. National Experiences

IP for Development – Indian Approach

Zakir Thomas

Project Director, Open Source Drug Discovery (OSDD) Unit
Council of Scientific & Industrial Research, New Delhi, India

OPEN SOURCE DRUG DISCOVERY

CSIR INDIA

Innovation Ecosystem

Components/Requirements

- **Skilled Human Resource**
- **Ability and Infrastructure to do R&D**
- **Legal System supporting innovation, including regulatory and IP framework**
- **Availability of venture capital**
- **Governmental Policies : Fiscal Policies that encourage Innovation**

IP Laws are Municipal Laws

Individuals act in their own self-interest – Adam Smith, Wealth of Nations

Nations Act in their own self Interest

Anna Karenina principle

Happy families are all alike; every unhappy family is unhappy in its own way

Two Sides of the Coin

THE HINDU

U.N body calls for balanced 'social benefit' IP regime

Francis Gurry

This can help reconcile differences:WIPO Director-General

TOPICS

economy, business and finance

The World Intellectual Property Organisation (WIPO), a United Nations body, has pointed out the need for a second interpretation of global intellectual property law, one that balances social benefit with the need to protect investment.

"I think there are two definitions of intellectual property. One has been defined by the need to innovate, and, therefore, the need to protect investment.

The second way is that it should not solely be about protecting the interests of investment, but instead should be about balancing social benefit with the whole mix,"

Dr. Francis Gurry, DG WIPO

Approach to IP Laws

Copyright Act 1957

Developing Country Concerns:

(i) Reward Authors
(ii) Access to Knowledge
(iii) Specific Cultural Context
(iv) Respect Local Industry Practices

- **Civil and Criminal Remedies**
- **Clearly Defined Fair Use Provisions**
- **Specific exceptions for use of music during marriage processions and religious festivals**
- **Producers of cinematograph films designated as 'author' based on Bollywood practices**

Copyright in Digital Age

- **Adopted WCT and WPPT Provisions**
- **Retains fair use provisions in digital age**
- **Safe Harbor for ISPs**

Special Provisions for Differently Abled: For Blind

Adaptation and reproduction of any work in any accessible format for private and personal; educational and research use;

By any not for profit organisation and individuals:
Compulsory licence for profitable purposes

Geographical Indications

Geographical Indications of Goods (Registration & Protection)Act, 1999

193 GIs registered in India

Broad Definition of GI: Handicraft Sector; local manufacturing sector:

Example:

Chanderi Silk (Madhya Pradesh, India)

- Localised style of handwoven saree production
- Mills started manufacturing and calling them Chanderi; they could make it cheaper; Chanderi was dying out; young generation dropping out
- GI granted in January 2005;
- 4000 families; improvement in socio economic condition in 2 years
- Compare with 15000 farmers of Champaign

Chanderi Silk Saree

Sui Generis Protection: The Protection of Plant Varieties and Farmer's Rights Act, 2001

To accelerate agricultural development, it is necessary :

- **to protect plants breeders' rights to stimulate investment for R&D for the development of new plant varieties**
- **to recognize and protect the rights of the farmers in respect of their contribution made at any time in conserving, improving and making available plant genetic resources and for the development of the new plant varieties**
- **Research exception and reuse exceptions to farmers**

PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS AUTHORITY, INDIA

Approach to IP Laws

Indian Patent Act

i. Clearly defined provisions for invention and what are not invention

ii. Provisions to prevent ever greening

iii. Provisions implementing Doha mandate

iv. Compulsory license

v. Bolar Exceptions

vi. Working Requirement

Indian Patent System: 100 years old

Ensure Deserving Inventions Gets Patent

A feature added while implementing TRIPS

- Pre Grant Opposition
  - anyone can oppose (no fee)
- Rationale: Limited resources: do not have resources of USPTO, so depends on community at large
- Ensuring Deserving gets Patents

- In addition, Post Grant Opposition

Indian Patent Law
Compulsory Licence: Grounds

- **Non-satisfaction of the reasonable requirements of the public**
  - **Refusal to grant licence on reasonable terms**
  - **Non-meeting demand for the product to an adequate extent or on reasonable terms**
- **Non-availability to the public at a reasonably affordable price**
- **Non-working in the country [Section 84]**
- ***Nothing could be worse for the country than that foreign patents should be protected in this country, while the industry is carried on abroad***

- Cripps, British Parliamentarian

First CL in India

- **Natco** Pharma requested for a CL for the anti-cancer drug **Nexavar** (*Sorafenib Tosylate)*, patented by **Bayer**
- Compulsory Licence granted in March 2012 on grounds
  - Bayer's import was grossly **inadequate to the needs** (hardly 2%)
  - No import in certain years
  - Company relying only on import and not local production, hence **not** meeting **working in India** condition
  - Price **not reasonably affordable** to the public
- Price Bayer **Rs. 2,80,428** ($5,500) for 120 tabs for a month; Natco to provide at **Rs. 8800** ($180)

Confirmed in Appeal by independent IP Appellate Board (March 2013): increased royalty to be paid by Natco to Bayer to 7%

Patent Act, India
Inventions Not Patentable: Section (3)

a) Frivolous, Contrary To Natural Laws

b) Contrary to Public Order or Morality, Prejudice to Human, Animal or Plant Life or Health or to the Environment;

c) Mere Discovery of Scientific Principle, Abstract Theory, Living Thing or Non-living Substances

d) Method of Treatment

e) Plants, Animals, Including Seeds Varieties, Species,

f) Biological Processes. Exception: Microorganisms

g) Mere discovery of microorganism is not patentable

h) Traditional Knowledge

Provisions to Prevent Evergreening

Section 3(d) reads as under:

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… is not invention within the meaning of the Act.

The Explanation to section 3(d) provides:

"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."

Meaning of Explanation to 3(d)

- **Each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph.**
- **These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention".**
- **Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance.**
- **In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy.**

Novartis Claim - Not Patentable

Claim in the Patent Application: beta crystalline form of Imatinib Mesylate, is inventive because:

- **(i) more beneficial flow properties,**
- **(ii) better thermodynamic stability, and**
- **(iii) lower hygroscopicity,**

Court

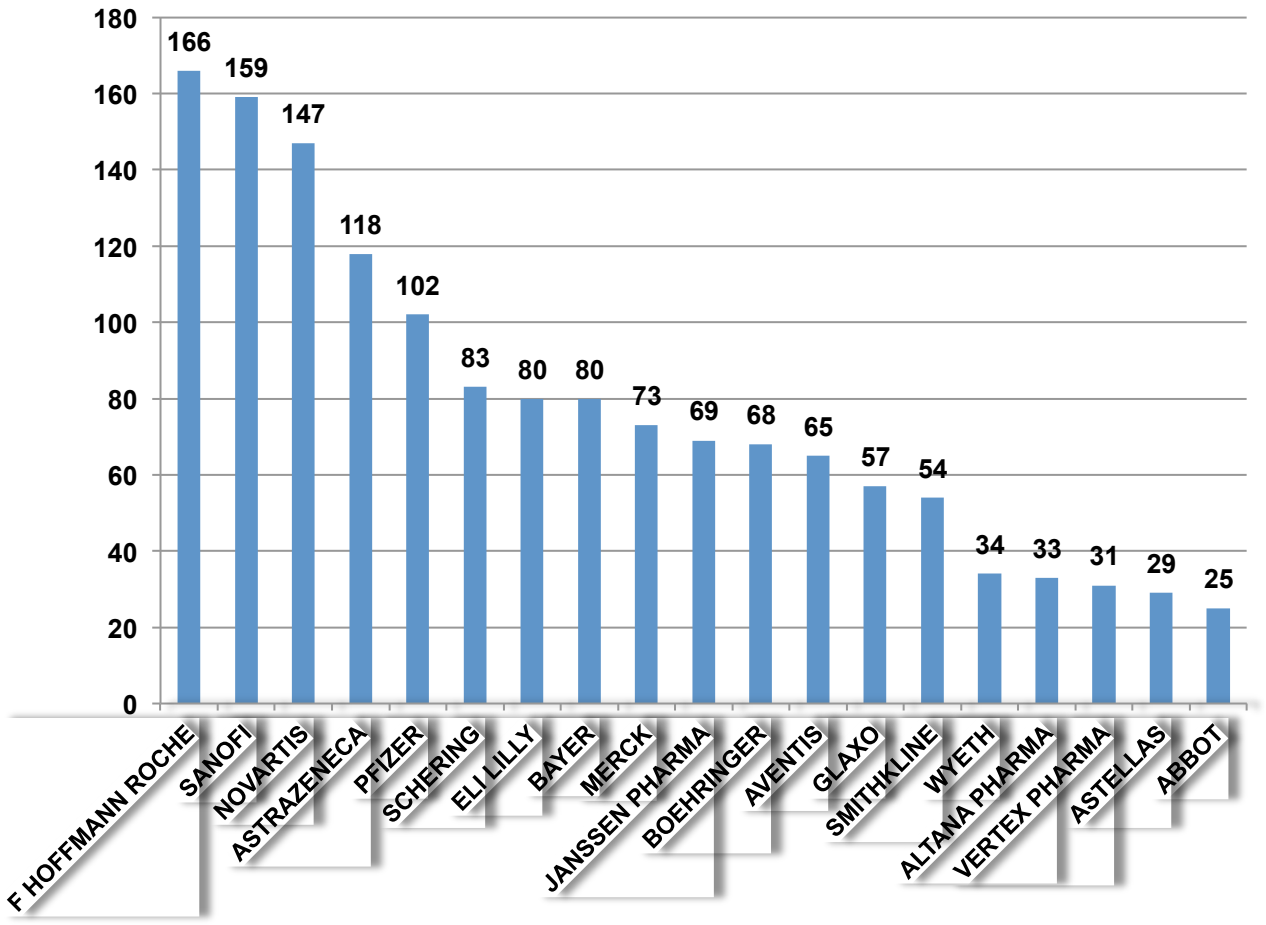
- **These are physico-chemical properties of Polymorphs (Beta Crystals)**
- **may be otherwise beneficial but … these properties have nothing to do with therapeutic efficacy**

Does 3(d) Prevent Incremental Innovation?

- **Section 3(d) does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances.**
- **"It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment". (para 191)**

Patents Granted to Research Based Pharma by Indian Patent Office

F HOFFMANN ROCHE	166
SANOFI	159
NOVARTIS	147
ASTRAZENECA	118
PFIZER	102
SCHERING	83
ELI LILLY	80
BAYER	80
MERCK	73
JANSSEN PHARMA	69
BOEHRINGER	68
AVENTIS	65
GLAXO	57
SMITHKLINE	54
WYETH	34
ALTANA PHARMA	33
VERTEX PHARMA	31
ASTELLAS	29
ABBOT	25



Between 2005- 2011, 4064 Patents were granted to Pharmaceutical Products; 12869 applications pending

: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)61513-X/

What Novartis Decision Means

THE HINDU

U.N body calls for balanced 'social benefit' IP regime

"While I don't want to comment on the Novartis decision, I think that, yes, an intellectual property regime that balances social benefit perhaps could be in the offing. In the end, it is basically a problem of variance in purchasing power between countries. There is a global market, but no global consumer as of yet,"

"In the end, the right balance must be found repeatedly. We will have more and more situations like Novartis in India, and we must see how IP can not only be about protecting investment, but also social benefit,"

Dr. Francis Gurry

Its about finding the right balance

Figure: http://www.selfishgiving.com/cause-marketing-news/striking-right-balance-of-philanthropy-marketing-business

Thank You