

**NATIONAL WORKSHOP :
PATENT AND PUBLIC HEALTH –
Addressing the Future Imperatives of Health
Security in the Post-TRIPS Era**

APRIL 11, 2005

ORGANISED BY :

**MINISTRY OF HEALTH AND FAMILY WELFARE
IN COLLABORATION WITH WHO**

PRESENTATION ON :

**HOW FAR THE TRIPS FLEXIBILITIES ARE
BEING ADDRESSED IN THE ORDINANCE**

BY :

**Mr. B.K. KEAYLA
CENTRE FOR STUDY OF GLOBAL TRADE
SYSTEM AND DEVELOPMENT
NEW DELHI**

IMPORTANT ISSUES FOR PRESENTATION

☞ SCOPE OF PATENTABILITY :

- DEFINITIONS, EXCLUSIONS
FROM PATENTABILITY &
PATENTABLE SUBJECT MATTER**

☞ ROLE OF DOMESTIC ENTERPRISES IN PATENTED PRODUCT

☞ EXPORT OF PATENTED PRODUCT

☞ LEGISLATIVE PROCESS OF AMENDING PATENTS ACT 1970

FREEDOM & FLEXIBILITIES AVAILABLE UNDER TRIPS AGREEMENT

☞ TRIPS PREAMBLE PROVIDES:

- **RECOGNISE – THE UNDERLYING
PUBLIC POLICY OBJECTIVES OF
NATIONAL SYSTEM FOR
PROTECTION OF IPR**

☞ ARTICLE 7 OBJECTIVES :

**IPR CONDUCTIVE TO SOCIAL &
ECONOMIC WELFARE AND TO
A BALANCE OF RIGHTS AND
OBLIGATIONS**

☞ ARTICLE 8 PRINCIPLES :

**IN AMENDING PATENT LAWS
ADOPT MEASURES NECESSARY TO
PROTECT PUBLIC HEALTH AND
NUTRITION AND PROMOTE PUBLIC
INTEREST IN SECTORS OF VITAL
IMPORTANCE**

DOHA DECLARATION ON TRIPS & PUBLIC HEALTH

☞ **DOHA DECLARATION PROVIDES :**

- **TRIPS BE INTERPRETED AND IMPLEMENTED IN MANNER SUPPORTIVE OF MEMBERS RIGHT TO PROTECT PUBLIC HEALTH AND TO PROMOTE ACCESS TO MEDICINES**
- **RIGHT TO GRANT AND FREEDOM TO DETERMINE GROUNDS FOR COMPULSORY LICENCES**

☞ **THE ABOVE PROVISIONS COULD HAVE BEEN KEPT IN VIEW IN AMENDING OUR PATENT LAW TO MAKE IT INDUSTRY & PUBLIC FRIENDLY**

SCOPE OF PATENTABILITY IN THE AMENDED ACT

■ DEFINITIONS :

- (2)(j) "INVENTION" MEANS A NEW PRODUCT OR PROCESS INVOLVING AN INVENTIVE STEP AND CAPABLE OF INDUSTRIAL APPLICATION
- (2)(ta) "PHARMACEUTICAL SUBSTANCE" MEANS ANY NEW ENTITY INVOLVING ONE OR MORE INVENTIVE STEPS

☞ BOTH THE ABOVE DEFINITIONS ARE BROAD

■ EXCLUSIONS OF INVENTIONS

- (3)(j) MICRO-ORGANISMS NOT EXCLUDED FROM PATENTABILITY
- POSITION ABOUT NON-BIOLOGICAL & MICROBIOLOGICAL PROCESSES UNCLEAR
- (3)(b) EXPLANATION :
OTHER DERIVATIVES OF KNOWN
SUBSTANCE SHALL BE CONSIDERED
TO BE THE SAME SUBSTANCE

☞ THESE EXPAND SCOPE OF PATENTABLE INVENTIONS

☞ SEC. 5 ON PATENTABILITY : OMMITTED

REASONS FOR CHANGES IN SCOPE OF PATENTABILITY

☞ OF UK COMMISSION ON IPR REPORT 2002 :

- **COUNTRIES ARE FREE TO DEFINE 'INVENTION' – NO DEFINITION IN TRIPS**
- **SCOPE OF PATENTABLE SUBJECT MATTER - TO BE LIMITED**
- **ABILITY OF PATENTEES TO PROHIBIT OTHERS FROM BUILDING ON OR DESIGNING AROUND PATENTED INVENTION - TO BE RESTRICTED**

☞ US FEDERAL TRADE COMMISSION REPORT 2003 :

- **VOLUME OF PATENT CLAIMS IN USA OVER THREE LAKHS PER ANNUM**
- **EXAMINERS 3000**
- **FLOOD OF CLAIMS BECOMING UNMANAGEABLE**
- **POOR QUALITY OR QUESTIONABLE PATENTS GRANTED**

☞ CHINA : PATENT CLAIMS – ALSO OVER 3 LAKHS PER ANNUM

REASONS FOR CHANGES IN SCOPE OF PATENTABILITY

(Contd.)

☞ **USA NATIONAL INSTITUTE FOR HEALTH
CARE MANAGEMENT RESEARCH &
EDUCATION FOUNDATION
REPORT 2002 :**

- **WIDE RANGE OF INVENTIONS –
INCREMENTAL MODIFICATIONS**
- **DISCOURAGING GENERIC COMPANIES**
- **BLOCKING COMPETITIVE PRODUCTS**

☞ **MASHELKAR COMMITTEE REPORT ON
PHARMACEUTICAL R&D :**

- **FOR PHARMACEUTICAL SECTOR
NEW CHEMICAL ENTITY / NEW
MEDICAL ENTITY ONLY TO BE
PATENTABLE**

SUGGESTED PATENTABILITY

■ DEFINITIONS :

☞ **(2)(j) INVENTION MEANS BASIC NOVEL PRODUCT OR PROCESS INVOLVING INVENTIVE STEP(S) AND CAPABLE OF INDUSTRIAL APPLICATION**

☞ **(2)(ta) PHARMACEUTICAL SUBSTANCE INCLUDES NEW CHEMICAL ENTITY OR NEW MEDICAL ENTITY INVOLVING INVENTIVE STEPS**

■ EXCLUSIONS :

☞ **(3)(j) MICRO-ORGANISMS, NON-BIOLOGICAL AND MICRO-BIOLOGICAL PROCESSES - TO BE EXCLUDED FROM PATENTABILITY -**

● **UNDER MANDATED REVIEW IN WTO**

● **ABSENCE OF DEFINITION**

☞ **(3)(d) EXPLANATION
.....DERIVATIVES OF KNOWN SUBSTANCE
SHOULD BE EXCLUDED FROM
PATENTABILITY**

SUGGESTED PATENTABILITY

(Contd.)

- ☞ AMENDED ACT PROVIDES OMITTING OF SECTION 5**
- ☞ PRESCRIBING OF SCOPE OF PATENTABILITY IMPORTANT**
- ☞ SECTION 5 SHOULD READ AS :
“PATENTS SHALL BE AVAILABLE FOR BASIC INVENTIONS INCLUDING PHARMACEUTICAL SUBSTANCES AS DEFINED IN SECTION 2 WHETHER PRODUCTS OR PROCESSES IN ALL FIELDS OF TECHNOLOGY PROVIDED THEY ARE NEW, INVOLVE AN INVENTIVE STEP AND CAPABLE OF INDUSTRIAL APPLICATION EXCLUDING INVENTIONS STIPULATED UNDER SECTION 3”**

ROLE OF DOMESTIC ENTERPRISES IN PATENTED PRODUCTS

☞ ARTICLE 31 OF TRIPS - USE (OF PATENT) WITHOUT AUTHORISATION OF RIGHT HOLDER

- 31(b) USE MAY ONLY BE PERMITTED
IF PRIOR TO SUCH USE, THE PROPOSED
USER HAS MADE EFFORTS TO OBTAIN
AUTHORISATION FROM RIGHT
HOLDER ON REASONABLE
COMMERCIAL TERMS AND
CONDITIONS AND THAT SUCH EFFORTS
HAVE NOT BEEN SUCCESSFUL WITHIN
A REASONABLE PERIOD OF TIME**

**☞ ABOVE PROVISION HAS BEEN IGNORED
IN AMENDING PROCESS OF OUR LAW**

**☞ PROVISION EXISTS IN PATENT LAWS OF
ARGENTINA, BRAZIL, CHINA, FRANCE,
GERMANY, UK AND OTHER COUNTRIES**

**☞ EXTREMELY IMPORTANT PROVISION FOR
EFFECTIVE ROLE OF OUR INDUSTRY –
AMENDMENT ABSOLUTELY
NECESSARY**

ROLE OF DOMESTIC ENTERPRISES IN PATENTED PRODUCTS

(Contd.)

- ☞ **SECTION 84 OF 1970 ACT DEALS WITH
ABUSE OF PATENT RIGHTS**
- ☞ **SUB-SECTION (6) STIPULATES :
CONTROLLER SHALL TAKE INTO ACCOUNT
WHETHER APPLICANT HAS
MADE EFFORTS WITH PATENTEE –**
 - **THIS IS MISPLACED CONDITION –
PATENTEE WILL NOT ENTERTAIN**
- ☞ **SECTION 85 REVOCATION OF COMPULSORY
LICENCE: CONDITION SHOULD BE ONLY NON-
WORKING AND NOT RELATED TO REASONABLE
REQUIREMENT OF PUBLIC, AVAILABILITY AND
PRICES**
- ☞ **NEED TO ISSUE MORE COMPULSORY
LICENCES**
- ☞ **SECTION 90 SUB-SECTION (6):
PROVIDES SHORTER TERM OF
COMPULSORY LICENCE – NOT JUSTIFIED**
- ☞ **ARTICLE 7 OF TRIPS PROVIDES :
TRANSFER AND DISSEMINATION OF
TECHNOLOGY –
NO PROVISION IN OUR LAW**

MAILBOX PRODUCTS

☞ **SECTION 11 (A) SUB-SECTION (7)
PROVIDES :**

**THOSE WHO ARE PRODUCING
MAIL BOX PRODUCTS PRIOR TO
1.1.2005 SHALL CONTINUE
PRODUCTION ON PAYMENT OF
ROYALTY – NO INFRINGEMENT
PROCEEDING AGAINST THEM**

☞ **ARTICLE 70.3 OF TRIPS STIPULATES:
THERE SHALL BE NO OBLIGATION
TO RESTORE PROTECTION TO
SUBJECT MATTER WHICH ON THE
DATE OF APPLICATION OF THIS
AGREEMENT FOR THE MEMBERS
IN QUESTION HAS FALLEN IN
PUBLIC DOMAIN**

☞ **MAILBOX PRODUCTS WHICH ARE
IN PRODUCTION AS ON 1.1.2005 ARE
IN PUBLIC DOMAIN – THUS NO
PATENT PROTECTION BE GRANTED**

AMENDED PATENTS ACT 1970
SECTION 92

☞ **SECTION 92 PROVIDES**
COMPULSORY LICENCE DUE TO -
CIRCUMSTANCES OF EXTREME
URGENCY

☞ **EXTREME URGENCY TO MEAN :**

- **HEALTH EMERGENCY - NATIONAL**
OR REGIONAL
- **ENVIRONMENT EMERGENCY -**
SOIL, AIR, WATER, ETC
POLLUTION

EXPORT OF PATENTED PRODUCT

- ☞ **IMPORTANCE OF ARTICLES 31(b) AND 31(f) OF TRIPS IMPORTANT FOR EXPORTS**
- ☞ **EXPORT DEMAND CAN BE MET BY DOMESTIC ENTERPRISES WHO ARE ALREADY PRODUCING RELEVANT PATENTED PRODUCTS**
- ☞ **IT TAKES THREE TO FOUR YEARS TO DEVELOP TECHNOLOGY AND STABILISE PRODUCT – TO MEET DOMESTIC AND EXPORT DEMANDS**
- ☞ **GRANT OF COMPULSORY LICENCE SOLELY FOR EXPORT - UNVIABLE DUE TO SMALL QUANTITIES – TIME FACTOR TO PRODUCE**

OPPOSITION PROCEEDINGS TO GRANT OF PATENTS

☞ **NEW SECTION 117 A PROVIDES :**

**IN SECTION 117A OF THE PRINCIPLE
ACT [AS INSERTED BY SECTION 47 OF
THE PATENTS (AMENDMENT) ACT,
2002], IN SUB-SECTION (2), FOR THE
WORDS AND FIGURES “SECTION 20,
SECTION 25, SECTION 27, SECTION 28,
THE WORDS, FIGURES AND BRACKETS
“SECTION 20, SUB-SECTION (4) OF
SECTION 25, SECTION 28” SHALL BE
SUBSTITUTED**

☞ **IMPLICATION:**

**APPEAL TO APPELLATE BOARD
EARLIER APPLIED TO PRE-GRANT
OPPOSITION NOW IT WILL APPLY
ONLY TO POST-GRANT OPPOSITION**

☞ **APPEAL FOR PRE-GRANT OPPOSITION
NEEDS TO BE RESTORED OTHERWISE
CONTROLLER WILL HAVE ABSOLUTE
RIGHT TO PRE-GRANT
REPRESENTATION**

LEGISLATIVE PROCESS OF AMENDING PATENTS ACT

- ☞ TRIPS ARTICLE 1 :
FREEDOM TO DETERMINE
APPROPRIATE METHOD OF
IMPLEMENTING TRIPS WITHIN
OWN LEGAL SYSTEM & PRACTICE**

- ☞ LEGISLATIVE SYSTEM PROVIDES :
REFERRING OF BILLS TO
STANDING COMMITTEE –APPLYING
OWN LEGAL SYSTEM AND
PRACTICE POSSIBLE**

- ☞ PATENTS (AMENDMENT) BILL 2005
PROVIDES ACT TO COME INTO
FORCE FROM 1.1.2005**

- ☞ WITH ENFORCEMENT DATE BEING
1.1.2005 RUSHING THE BILL NOT
JUSTIFIED**

- ☞ STANDING COMMITTEE SHOULD NOW
REVIEW THE AMENDED ACT FOR
FINE TUNING**

Speech delivered by Mr.Z. H. Charna, Director, OPPI at the National Workshop on Patent and Public Health – Addressing the Future Imperatives of Health Security in the Post – TRIPS Era

11th April, 2005

Casurina Hall, India Habitat Centre, New Delhi

Effect of the new Patent regime on prices of medicines

Several myths have been propounded by the anti-Patent lobby. Most of these are based on conjecture and are unsupportable on facts.

A myth is propagated that after introduction of the new Patent Act, 2005 in compliance with TRIPs provisions, the prices of medicines will accelerate and medicines will become unaffordable for the common man.

This fear is due to a lack of understanding, very often due to a deliberate lack of understanding of how the transition to a Patent Regime works and how pharmaceutical prices are determined. Patents can never be awarded retrospectively. Patents can only apply to new discoveries. The transition provisions of TRIP's ensure that patents in India will only be granted for totally new discoveries, post 1st January 1995. Since patents of over 95% of the drugs available in India have expired and there are no patented drugs in the WHO List of Essential Drugs, these drugs will continue to be available at current prices. Also, the National Pharmaceutical Pricing Authority (NPPA) has power to control the prices of even decontrolled drugs if found excessive.

It should be noted that it takes anywhere between 10-15 years for a new drug to be granted registration by Drug Authorities of any country after which marketing permission is given. This registration period comes out of the overall patent life of the medicines, which is now almost universally 20 years from the date of application. A discoverer thus enjoys at best only 5-10 years of Exclusive Marketing for recovering the cost of research. The number of new drugs registered worldwide each year is only between 25-35.

What this essentially means is:

- A. Within the transition period (1995-2004) allowed for India, not more than a handful of new drugs will actually qualify for any form of exclusivity.
- B. Even after India commences granting patents, by the time patented products become a significant proportion of those already available locally; it will be another 10-15 years i.e. 2015-2020.
- C. It is not correct to believe that Multinational Corporations (MNCs) have only one price for a product every where in the world and as such the prices charged in India will be exorbitant. There are several examples to show that even when the product is unique, it is introduced in India at a price significantly lower than in Western countries. Most international manufacturers will base their pricing strategy for countries, like India, on "affordability criteria".

There is empirical evidence (Study by the National Economic Research Associates –NERA, Washington – January 1998 and the Study by Dr. Heinz Redwood entitled 'New Horizons in India' - 1994) to show that prices do not rise after IPR.

A study of prices in 6 therapeutic categories (anti-ulcerants, anti-depressants, calcium antagonists, non-narcotic analgesics, broad-spectrum penicillins and ACE inhibitors) in 9 countries : (South Korea, Mexico, Hungary, Taiwan, Brazil, Argentina, Egypt, Jordan and Turkey) demonstrates that strengthening IPR does not have a measurable impact on real or nominal prices of existing drugs. Globally, only 25 to 35 new drugs enter the market every year and only a few of them are commercial successes. At the same time, each year patents expire for earlier products. On an average therefore, there will not be more than 15 to 20 patented products in any market. Newer products, being more effective, ultimately lead to lower per day cost of therapy to the patient. Beyond all these, in India drug prices are administered by the Government.

The difficulties which developing countries have in providing access to vital medicines for their populations clearly suggest that there is no single factor that constitutes a barrier to improved healthcare.

As far as the association between patent status and price level is concerned, it is to be noted that while patents do have an effect on price, this effect is not in general relevant to the healthcare problems of the underdeveloped world for the following reasons:

- i. There are very few patented products in the armamentarium needed for the improvement of developing country healthcare status. All the products on the Essential Drug List of WHO are off-patent.
- ii. Where patented products are important (e.g. for HIV/AIDS), manufacturers are actually seeking to offer special prices which have regard to economic and social realities (e.g. in the context of the UN-led Accelerating Access Initiative - for which 72 countries worldwide had expressed interest, prices of some antiretroviral drugs had been cut on an average by 85%). Pharmaceutical companies have individually been offering substantially reduced prices on medicines and vaccines to developing countries for many years, and the industry is committed to continue and extend these efforts.
- iii. Patent medicine prices are not a *per se* cause of healthcare problems or of limited access. Indeed, many examples show that absence of patents does not automatically create affordable price levels. Even off-patent drugs supplied by generic manufacturers are unaffordable or in short or intermittent supply.
- iv. The cost of the drug itself is in any case minimal compared to the entire cost of effectively distributing, administering and monitoring its use.
- v. **The main causes of limited access to medicines are undoubtedly poverty -- the under funding of healthcare systems -- and the lack of developed medical infrastructure in many of the countries concerned.**

Therefore, to attack intellectual property rights vested in patents or to presume that there must necessarily be excessive prices is patently wrong, and gives rise to policy ideas which, if implemented, would quite simply fail to achieve the intended objective, shared by all, of better health in the developing world.

Although patented medicines are not prominently important in the global issue of improving access to health, patents are essential as they incentivise research-based pharmaceutical companies to invest in the development of new and better treatments, including for diseases prevalent in the developing world.

I shall sum up by recapitulating in brief, the reasons for prices not going up:

1. Globally 25-35 drugs enter the market each year. Only few of them succeed commercially.

2. At any point of time only 5-7% of drugs in the world market are under patent protection. The rest, 93-95 % market is of generics
3. For any new patented medicine, there are a minimum of 6-10 generic equivalents available
4. The price difference between the two itself acts as a control on patented drugs.
5. In India, most patients pay out of their pockets. Their limited purchasing power will also act as a check on prices.
6. One cannot compare prices of patented medicines in US & UK with those in India. In those countries, the consumers mostly do not pay. The Insurance companies pay. India's per-capita income is also far less.
7. Drugs (Price Control) Order 1995 is very effective in India. There is a 3-tier control. Government can fix prices of even decontrolled medicines under para 10 (b) of DPCO 1995
8. The provisions of Compulsory Licencing and Parallel Imports in the new Patent Act, will also help the common man, by keeping prices at a realistic level.)
9. Drugs patented before 1st January 1995 will not be patentable and will continue to be available as generics.
10. All drugs in the WHO list of Essential Medicines are off-patent.
11. The 400 odd drugs listed in our own Health Ministry's List of Essential Medicines, are also off patent.
12. Indian copiers of molecules pending in the mail box will continue to manufacture and market them till patents are granted to the inventor, after three or four years that too prospectively. After that they will have to only pay a reasonable royalty and continue to market these drugs.

It is, therefore, patently wrong to say that prices of medicines will increase under the new Patent Regime.