

STATUS OF PHARMA INDUSTRY IN INDIA

Chart 2

PRODUCTION, IMPORT & EXPORT

Indian Rupees in Million

YEAR	BULK DRUGS	FORMU-LATIONS	IMPORTS	EXPORTS
1999-00	37,770	158,600	15,020	72,302
2000-01	45,330	183,540	20,325	87,299
2001-02	54,390	211,040	25,812	104,759
2002-03	65,290	241,850	11,025	119,250
2003-04	77,790	267,920	-	-

MANAGEMENT OF IPR

Chart 3

VOLUME

- **PRESENT VOLUME IN INDIA 1415 IN 2003-04**
- **VOLUME IN CHINA : 308487 IN 2003**
- **VOLUME IN USA OVER 3,00,000**
- **MANAGED IN USA BY 3000 EXAMINERS**

INDIAN STRENGTH OF EXAMINERS ONLY 150

- **SIMILAR VOLUME IN INDIA UNMANAGEABLE, CHAOS**
- **VOLUME TO BE CONTAINED**

PATENT APPLICATIONS FILED IN INDIA & PCT

Chart 4

YEAR	INDIA	FOREIGH	TOTAL	PCT
1999-00	724	312	1036	34
2000-01	716	463	1179	1140
2001-02	786	444	1230	1714
2002-03	870	310	1180	1872
2003-04	1151	264	1415	1029

**PATENT APPLICATIONS FILED
IN CHINA (SIPO)**

Chart 5

Sr.No.	Year	Domestic	Foreign	Total
1.	1999	109958	24281	134,239
2.	2000	140273	30417	170,690
3.	2001	170125	33448	203,573
4.	2002	205633	46998	252,631
5.	2003	251238	57249	308,487

MANAGING IPR MEANS

Chart 6

- **ADEQUATE STRENGTH OF EXAMINERS**
- **EXAMINATION OF APPLICATIONS**
- **MANAGING PRE GRANT OPPOSITIONS**
- **PATENT PERIODICAL RENEWALS**
- **MANAGING COMPULSORY LICENCE APPLICATIONS**
- **MANAGING DISPUTES**
 - **THROUGH TRIBUNAL**
 - **THROUGH COURTS**
 - **THROUGH CONTROLLER**
- **CONTROLLING INFRINGEMENTS**
- **PATENTS SHOULD NOT BE FREELY GIVEN. CONTAIN SCOPE**

HOW TO MANAGE IPR

Chart 7

☞ DEFINITIONS OF PATENT TERMINOLOGIES

- INVENTIONS – BASIC &
NOVEL
- NOVELTY : SUBJECT MATTER
 - NOT FALLEN IN PUBLIC
DOMAIN
 - NOT PART OF PRIOR
ART
- PATENTABLE PHARMACEUTICAL
SUBSTANCES :
 - NEW CHEMICAL ENTITY
 - NEW MEDICAL ENTITY
- NO FRIVOLOUS CLAIMS
SUCH AS FORMULATIONS, ETC

SCOPE OF PATENTABILITY

Chart 8

PROVISION IN LAW

“PATENTS WOULD BE AVAILABLE FOR BASIC NOVEL INVENTIONS INCLUDING PHARMACEUTICAL PRODUCTS AND PROCESSES, IN ALL FIELD OF TECHNOLOGIES BUT EXCLUDING INVENTIONS NOT PATENTABLE, PROVIDED THAT THEY ARE NEW, INVOLVE INVENTIVE STEP AND ARE CAPABLE OF INDUSTRIAL APPLICATION”.

IMPORTANT PROVISION FOR COMPULSORY LICENCE

Chart 9

FORMULATION OF PROVISION BASED UPON ARTICLE 31 OF TRIPS.

“WHERE THE PROPOSED USER HAS MADE EFFORTS TO OBTAIN AUTHORISATION FROM THE PATENTEE TO USE THE PATENT ON REASONABLE COMMERCIAL TERMS AND CONDITIONS AND WHERE SUCH EFFORTS HAVE NOT BEEN SUCCESSFUL WITHIN A REASONABLE PERIOD OF TIME, THE CONTROLLER SHALL AT ANY TIME AFTER THE EXPIRATION OF THREE YEARS FROM THE GRANT OF THE PATENT, GRANT COMPULSORY LICENCE TO THE APPLICANT ON SUCH TERMS AND CONDITIONS AS HE MAY DEEM FIT”

EXPORT OF PATENTED PRODUCT

Chart 10

- **TRIPS PROVIDES COMPULSORY LICENCE PREDOMINANTLY FOR DOMESTIC MARKET**
- **THIS PROVISION PROVIDES SCOPE FOR EXPORTS**
- **PARA 6 PROCEDURE COMPLICATED UNWORKABLE**
- **LICENSEE FOR DOMESTIC PRODUCTION CAN ONLY MEET SMALL EXPORT DEMANDS**
- **EXPORT ONLY OF SMALL QUANTITIES UNVIABLE**