## STATUS OF PHARMA INDUSTRY IN INDIA

### Chart 2

### PRODUCTION, IMPORT & EXPORT

<table>
<thead>
<tr>
<th>YEAR</th>
<th>BULK DRUGS</th>
<th>FORMULATIONS</th>
<th>IMPORTS</th>
<th>EXPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999-00</td>
<td>37,770</td>
<td>158,600</td>
<td>15,020</td>
<td>72,302</td>
</tr>
<tr>
<td>2000-01</td>
<td>45,330</td>
<td>183,540</td>
<td>20,325</td>
<td>87,299</td>
</tr>
<tr>
<td>2001-02</td>
<td>54,390</td>
<td>211,040</td>
<td>25,812</td>
<td>104,759</td>
</tr>
<tr>
<td>2002-03</td>
<td>65,290</td>
<td>241,850</td>
<td>11,025</td>
<td>119,250</td>
</tr>
<tr>
<td>2003-04</td>
<td>77,790</td>
<td>267,920</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
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**
<table>
<thead>
<tr>
<th>YEAR</th>
<th>INDIA</th>
<th>FOREIGN</th>
<th>TOTAL</th>
<th>PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999-00</td>
<td>724</td>
<td>312</td>
<td>1036</td>
<td>34</td>
</tr>
<tr>
<td>2000-01</td>
<td>716</td>
<td>463</td>
<td>1179</td>
<td>1140</td>
</tr>
<tr>
<td>2001-02</td>
<td>786</td>
<td>444</td>
<td>1230</td>
<td>1714</td>
</tr>
<tr>
<td>2002-03</td>
<td>870</td>
<td>310</td>
<td>1180</td>
<td>1872</td>
</tr>
<tr>
<td>2003-04</td>
<td>1151</td>
<td>264</td>
<td>1415</td>
<td>1029</td>
</tr>
<tr>
<td>Sr.No.</td>
<td>Year</td>
<td>Domestic</td>
<td>Foreign</td>
<td>Total</td>
</tr>
<tr>
<td>-------</td>
<td>------</td>
<td>-----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
<td>1999</td>
<td>109958</td>
<td>24281</td>
<td>134,239</td>
</tr>
<tr>
<td>2.</td>
<td>2000</td>
<td>140273</td>
<td>30417</td>
<td>170,690</td>
</tr>
<tr>
<td>3.</td>
<td>2001</td>
<td>170125</td>
<td>33448</td>
<td>203,573</td>
</tr>
<tr>
<td>4.</td>
<td>2002</td>
<td>205633</td>
<td>46998</td>
<td>252,631</td>
</tr>
<tr>
<td>5.</td>
<td>2003</td>
<td>251238</td>
<td>57249</td>
<td>308,487</td>
</tr>
</tbody>
</table>
MANAGING IPR MEANS

- 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

DEFINITIONS OF PATENT TERMINOLOGIES

• INVENTIONS – BASIC & NOVEL

• NOVELTY : SUBJECT MATTER
  • NOT FALLEN IN PUBLIC DOMAIN
  • NOT PART OF PRIOR ARD

• PATENTABLE PHARMACEUTICAL SUBSTANCES :
  • NEW CHEMICAL ENTITY
  • NEW MEDICAL ENTITY

• NO FRIVILOUS CLAIMS SUCH AS FORMULATIONS, ETC
SCOPE OF PATENTABILITY

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”.

Chart 8
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