

Patents, TRIPS+ & a Reality Check

*“Pharma Cos must get ready
to face the challenges.... ”*

Presentation At
An R&D Centre in Bangalore,

April 29, 2004

The Challenges Ahead.....

Transition from a 35 years old soft-patent regime to a hard patent regime

The TRIPS/WTO Deadline of December 31, 2005

Product Patents for all types of Inventions by January 1, 2005

Untested principles of local working and compulsory licenses

Tested patent prosecution strategies of major pharmaceutical companies

Tested Patent Enforcement Strategies of overseas pharmaceutical companies

Lack of IP preparedness

Absence of a competent patent bar



Indian Pharma Cos are gearing up.. US PATENT STATISTICS*

Company	Number of Patents Published Since March 15, 2001	Number of Issued Patents
Ranbaxy Laboratory	—	30
Dr. Reddy's Research Foundation	—	55
Panacea Biotech Limited	8	24
Dabur Research Foundation	2	18
Biocon India Limited	—	11
Lupin	1	11
Cadila Health Care	1	1
Cadila Pharmaceutical limited	1	1
Wockhardt Limited	6	1
Wockhardt Europe Limited	—	3

Ranbaxy
Current Statistics - US, AU & EPO

Country	United States	Australia	Europe
No. of Patents Issued	55	67	48

Indian Patent Statistics - European Chemical Majors

Serial No.	Name of the Company	Number of Patent Applications accepted between 1.1.1995 and 31.12.2002
1	MERCK PATENT GMBH	116
2.	AKZO NOBEL NV	138
3.	CIBA SPECIALITY CHEMICALS HOLDING INC,	103
4.	COGNIS DEUTSCHLAND GMBH	7
5.	DEGUSSA HULS AKTIENGESELLSCHAFT	112
6.	DSM N.V	100
7.	HENKEL KOMMANDITGESELLSCHAFT AUF AKTIEN	110
8.	HERAEUS GMBH	12
9.	NOVO NORDISK A/S	362
10.	NOVOZYMES	3
11.	PFIZER INC	205
12.	F HOFFMANN-LA ROCHE AG	229
13.	SHELL INTERNATIONALE RESEARCH MAATSCHAPPIJ B V	215
14.	SYNGENTA PARTICIPATIONS AG SWITZERLAND	23

Patent Statistics – India Pharma Cos

SERIAL NO.	NAME OF THE COMPANY	NUMBER OF PATENT APPLICATIONS ACCEPTED BETWEEN 1.1.1995 AND 31.12.2002
1	ALEMBIC LIMITED	40
2.	ASTRA ZENECA AKTIEBOLAG	2
3.	BIOCON LIMITED	43
4.	CADILA HEALTHCARE LTD	29
5.	CADILA PHARMACEUTICALS LIMITED	41
6.	CIPLA LTD	50
7.	LUPIN LABORATORIES LTD	52
8.	PANACEA BIOTEC LTD	128
9.	RANBAXY LABORATORIES LTD	175
10.	SUN PHARMACEUTICAL INDUSTRIES LIMITED	97
11.	JUBILANT ORGANSYS LIMITED	7
12.	WOCKHARDT RESEARCH CENTRE	17

Medicines & Drugs - The EMR Story

- **The Patents (First Amendment) Act, 1999**
- **The Patents (Second Amendment) Bill, 1999**
- **The Patents Amendment Act, 2002**
- **The Patents (Amendment) Bill, 2004 (drafting underway)**
- **January 1, 1995 – India joins WTO**
- **January 1, 1996 – General Period to conform to TRIPS**
- **January 1, 2000 – Period for Developing Country Members to conform to TRIPS**
- **January 1, 2005 for those Developing Country Members not having product patent for certain categories of inventions of the date of application of WTO Agreement**
- **1 January 1995 – Transitional Protection for Pharmaceutical & Agricultural Chemical Products from the Date of Entry into WTO**

Applicant	Title of the EMR/Patent Application and related Drug Product	Brand Name	Status	Application No	Patent no for the EMR
Glaxosmithkline Beecham	Rosiglitazone (Novel compounds)	Avandia	EMR rejected	EMR/3/2000 - 30/06/2000	2505/DEL/98 dt 25.08.1998
Glaxo Smithkline Beecham	Novel compounds (name of drug product not available)	Not known	EMR Rejected	EMR/2/2000-30/06/2000	2504/DEL/98 dtd 25.08.98
Novartis	Imatinib mesylate	Glivec	EMR granted (the first EMR in India)	EMR/1/2002-27-03-2002	1602/MAS/98 dtd 17.07.98
Wockhardt	Nadifloxacin	Nadoxin	EMR granted		
United Phosphorus	Combination of Carbedazim & Macozeb	SAAF	EMR granted (first EMR of an Indian company)		
Nicolas Piramal	Aablaqine	Bulaquine	EMR Application Pending	EMR/2/2003-16/10/2003	501/MUM/00 dtd 31-05-00
Hoffman-La-Roche	Saquinavir mesylate	Invirase	EMR rejected		910/MAS/1996 dt 28-5-1996
Eli-Lilly	Tadalafil	Cialis	EMR Application Pending		
Astra Zeneca	Gifitinib	Iressa	EMR Application Pending		
Astra Zenca	Ximelagatran	Exanta	EMR Application Pending		
Wockhardt	Pharmaceutical compositions containing Benzoquinolizines	Not known	EMR Application Pending	EMR/1/2003 dtd 17-07-2003	308/MUM/2002 DTD 28 TH March 2002
Schering Plough	Biotech – interferon alpha	Not known	EMR Application Pending		
Bristol-Myers Squibb	Gatefloxacin	Tequin	EMR Application Pending		
Bayer	Moxifloxacin	Avelox	EMR Application Pending		
Novartis	Zoledronic acid	Zometa	EMR Application Pending		
Ranbaxy	Once-a-day oral controlled release form	Ciprofloxac in	EMR Application Rejected	EMR/4/2001	
Eli Lilly	Tetracyclic derivatives, process for preparation and use thereof	Not known	EMR Application Pending	EMR/3/2003	85/DEL/1995 dtd 23/01/1995

8/6/2005

The recent developments

- The 2002 Act makes the national law close to TRIPS
- This amendment has come into effect on May 20, 2003
- “Invention” has been redefined to mean: “a new product or process involving an inventive step and capable of industrial application”.
- The new definition is in conformity with Art.27 of the TRIPS Agreement.
- This definition considerably broadens the meaning and content of “invention” for purposes of ascertaining patentability”

The coverage of subject matters excluded from the scope of patentability has been expanded:

The following subject matters, *inter alia* are not patentable:

- ❑ Plants or animals in whole or part thereof;
- ❑ Seeds, varieties and species;
- ❑ Essentially biological processes for production or propagation of plants or animals
- ❑ Mathematical methods, business methods, algorithms and computer program per se;
- ❑ Literary, dramatic, artistic work or any other aesthetic creation;
- ❑ Methods of playing a mental act or method of playing games;
- ❑ A presentation of information;
- ❑ Topography of IC Chips;
- ❑ Invention which in effect is traditional knowledge.

Definition of “Medicine or Drug” has been amended.

- “Medicine or Drug” includes :
 - All medicines for internal or external use of human beings or animals
 - All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in humans of
 - All substances intended to be used in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals
 - Insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants
 - All chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred.

Pharmaceutical Chemical Agricultural Chemical Related Inventions

- ❑ The expanded definition of “Medicines or Drugs” has direct bearing on the patentability of inventions claiming “medicine” or “drug”.
- ❑ The definition of “medicines” or “Drugs” must be read in the light of the currently available limited term patent protection or Exclusive Marketing Rights
- ❑ Pharmaceutical Companies are not keen to avail the transitional protection because of the stringent eligibility criteria to get EMRs
- ❑ Currently product patent applications for medicines and drugs go to the Mail Box which will be open only after 31 December 2004.
- ❑ The new amendment makes it clear that the limited term patent protection until January 1, 2005 and the compulsory licensing provisions will apply to agri-chemicals as well

Industry friendly Amendments

- ❑ Term of Patent extended from 14 years to 20 years
- ❑ First Filing outside India is permissible
- ❑ Request for Examination possible
- ❑ Publication of Patents on completion of 18 months
- ❑ IP Appellate Board to hear appeals from the orders of Controller and also to hear patent revocation petitions

Patent System Getting Streamlined

- The Indian Patent System is getting streamlined
- The Patent Offices have been fully automated
- 350 new Patent Examiners have joined
- A Training Institute has been set up in Nagpur at the Patent Information Bureau
- The backlog of pending patent application will be cleared soon
- An Intellectual Property Appellate Tribunal has been set up. The IP Appellate Tribunal will hear appeal from the decision of the Controller of Patents
- The Institute of Microbial Technologies at Lucknow has been designated as the International Depository Authority for the disclosure of biological materials (microorganisms) under the Budapest Treaty

IP Preparedness at Strides...

- ❑ Do you have an IPR Policy
- ❑ Do you have a senior management committee on IPRs
- ❑ Do you have a patent cell
- ❑ Do you have an IPR – R&D documentation policy
- ❑ Do you have a docket retention policy
- ❑ Do you do IP mining
- ❑ Do you have capability to do structured patent search
- ❑ Do you structure your R&D plans based on patent competitive analysis search
- ❑ Do you do patent mapping

Thank You