

MDN

## Management Of Confidential Information- Current Scenario

**M.D. Nair**

**Bangalore**

**February 9, 2006**

MDN

## An Assumption & A Caveat

Assumption :  
Confidential Information referred to in the Title is primarily related to The Healthcare Business, of which Drugs and the Pharmaceuticals Industry are important Components.

Caveat:  
Discussions therefore will centre around the contentious issues related to the protection of Undisclosed Information (Trade Secrets) as defined under TRIPS.

MDN

## Realities Of Health Care Systems

- Sickness, Doctors, Drugs and Industry will continue to have an alliance, however unholy it would appear to be.
- The gap between real medical needs and profitable markets will continue.
- Large MNCs will invest in R&D for new drugs only in areas which will ensure adequate Returns On Investments (ROI).
- Developing countries' special problems will not be the areas of R&D investment by MNCs.
- Tertiary and sophisticated hospitals will serve few at the cost to many.
- Many new Diseases & Epidemics will continue to emerge.
- In spite of all advances, overall morbidity rates will remain same.

MDN

## Stating The Problem From The R&D- Driven Pharmaceutical Companies' Perspective

- New Drugs are needed to treat diseases for which no drug exists or the existing drugs are not effective and/or are too toxic for human use.
- New drug discovery is the most expensive and non-productive component of the Industry's investments.
- The cost of a new drug reaching the market place has been estimated to be between \$ 800 mio and \$ 1.5 mio.
- Leading Pharma Companies spend 12-20% of their turnover annually on drug research with the largest ones, each spending over \$ 5 bio per year on this activity.
- For these reasons R&D-based Pharma Companies argue for legal provisions for all protection systems for their Intellectual Capital, to enable them recover their costs.

MDN

## The Global Pharmaceutical Industry Majors Are At The Cross Roads. The Biggest Bottleneck For Growth Is The Poor Pipeline Of New Products And The High Costs Of Discovering & Developing Them

MDN

## WHY THE COSTS ARE HIGH More Stringent Clinical Trials

	1984-85	1994-95
Average No. of Clinical Trials / NDA	30	68
Average No. of Patients per NDA	1,321	4,237

**MDN**

**Time (In Years) To Develop A New Drug (Average) Pre-Clinical Testing To Approval 1963-1998**

	Pre-clinical Phase	Clinical Phase	Approval Phase
1960s	3.6	2.8	2.4
1970s	4.6	4.4	2.1
1980s	4.7	5.7	2.8
1990s	4.7	6.6	1.9

**MDN**

**Can We Make Regulatory Submissions More Crisp And Meaningful**

No. of Words In Documents

Pythagoras Theorem	24
Archimedes Principle	67
The Ten Commandments	179
American Declaration of Independence	300
European Legislation on when and where one can smoke	24,942
Average IND Submission to FDA	800,000

- MDN**
- Pitfalls Of The Current Western Model**
- High and unaffordable costs of R&D and consequently of new drugs.
  - Too many products with identical pharmacological profile and mechanism – the milligram battle.
  - Low therapeutic rationale and advance for new drugs.
  - Many products especially biotech products developed through technology push rather than medical demand pull.

- MDN**
- WISHLIST OF GLOBAL PHARMA COMPANIES**
- Produce more effective drugs for wider range of diseases at less cost.
  - Extend the exclusivity in the market to maximum .
  - Speed up drug approvals and commercialisation to ensure longer patent protection.
- To make Drugs R&D more affordable the strategy has been to effect mergers of the majors in the hope that bigger is better and more productive.

**MDN**

**How Big Can You Grow?**

Ciba-Geigy-Sandoz (Novartis)  
 Marion-Merrill-Dow-Hoechst Roussel-Rhone Poulenc-Rorer - Sanofi (Aventis)  
 Richardson-Merrell-Proctor & Gamble  
 Kabi-Pharmacia-Upjohn  
 Bristol-Myers-Squibb  
 AHP-American Cynamide  
 Astra-Zeneca  
 Bayer-Sterling  
 Glaxo-Burroughs Wellcome- SKB  
 BASF-Knoll-Boots  
 Roche-Syntex  
 Pfizer – AHP-Pharmacia Upjohn

**MDN**

**In Pharma Business Like Everywhere Else There Are Davids And Goliaths**

Large MNCs are becoming Goliaths by mergers and believe that bigger is better.

Others believe that Davids are effective too:  
 Look at Amgen, Genentech, Janssen, etc.

The Goliaths cast a wide net to catch big fish, but in the process, their boats might capsiz.

India can take only 'David' Route.

**To become Davids, new strategies are required.**

**In the old Darwinian economics, the big ate the small – in the future, the fast will eat the slow.**

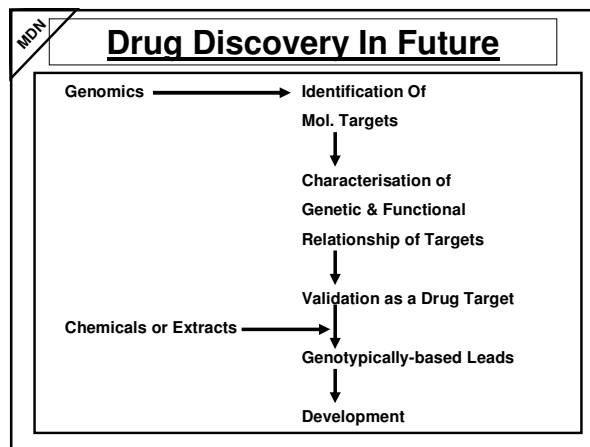
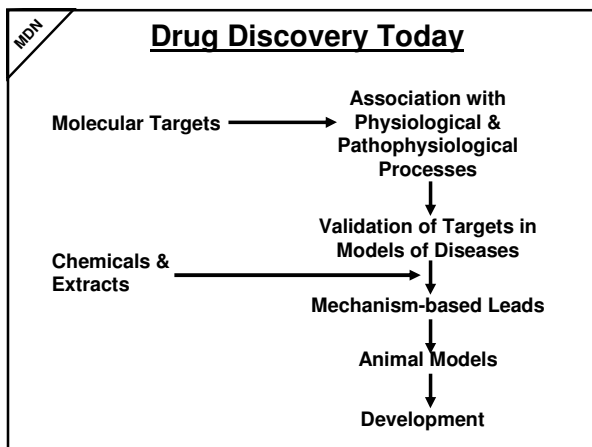
**Pharma Industry instead of growing in size should increase its creativity quotient.**

**More Intelligent Ways Have So Far Not Resulted In Lower Costs Of R&D.**

**Evolution Of R&D Approaches:**

- 1) Random Screening Of large number of molecules (hit & miss)
- 2) Rational Design based on Structure-Activity Correlation.
- 3) Screening against Molecular Targets.
- 4) Based on Genomics, Proteomics & Gene Therapy

While the new approaches can lead to more specific and better drugs, in terms of time required for drug discovery & development, the costs involved or the amount of data to be generated for approval, they have not been more effective.



**Role Of Confidential Information**

The terms Confidential Information, Trade Secrets and Undisclosed (Confidential) Information are used synonymously . Its Source could be from any of the activities of a Corporation, R&D, Manufacturing, Marketing and Commercial.

Protection of such Information from third party use for commercial purposes is considered essential for the owner of the information to exclusively use it and reap benefits.

**Is Confidential Information / Trade Secrets A Form Of Intellectual Property(IP) ?**

Whether it is or not, laws are needed to protect them from theft.

**Maintenance of secrecy is implicit (though not legally) in certain relationships.**

**Eg., Between:**

- Solicitor & Client
- Director and Company
- Partners in Business
- Employer & Employee

**MDN**

### How To Protect Your Confidential Information From Piracy\*\*

- Legal ways through appropriate legislations.
- Moral ways by inculcating values.
- Bonded approach.
- Secrecy modalities.

\*\* Of these only the legal means can be enforced.

**MDN**

### In The Absence Of A Legal Remedy Can A Secret Be kept Secret From All And for All Time? The Case Of Coca-Cola

The best known case of keeping a technology secret is that of Coca-Cola.

The Formula Of Coca-Cola is known at any one time only to two employees, whose names are not revealed to anyone except the Chairman.

They are not allowed to go on leave together or even to fly on the same Airplane .

So far the system has worked well for the last seven decades.

However this is not a Model which can be easily followed by others.

**MDN**

**Legal means have been available in a number of WTO Member Countries since the late 80's (long before WTO came into being).**

**The concept was also endorsed under Art. 39 of TRIPS Agreement, a component of GATT signed at Marrakesh in April 1994.**

**MDN**

### Protection Of Trade Secrets (TRIPS)

Art. 39 : To ensure effective protection against unfair competition as provided in Art 10bis of the Paris Convention (1967), Members shall protect undisclosed information as long it is:

- A secret, has commercial value because it is a secret, and has been subject to reasonable steps by the person legally in control of the information, to keep it a secret.
- Submissions made to Government for various regulatory approvals shall be protected against disclosure for commercial use except where necessary to protect public interest.

**MDN**

### Article 39.3 Of TRIPS\*\*

“Members when requiring as a condition of approving the marketing of pharmaceuticals or agricultural chemical products which utilise new chemical entities the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, members shall protect such data against disclosure except where necessary to protect the public or unless steps be taken to ensure that the data are protected against unfair commercial use”.

\*\* Underlined Terms Ambiguous

**MDN**

### Ambiguities In Art. 39.3 Of TRIPS

- 1) The Article does not specify the minimum period for which protection has to be assured.
- 2) Does the term “ unfair commercial use” include use by the Regulatory Agencies to assess the application of a generic manufacturer ?
- 3) What is the definition of :
  - Other Data
  - New chemical entities
  - Considerable effort
  - Protect the public

**MDN**

**To Decide whether something is a secret, in case of a dispute, the Court will consider whether:**

- 1) Information was the property of the company and was confidential to the company.
- 2) Information was let out in breach of a promise or contract to keep it confidential.
- 3) Information was used in a manner which has resulted or can result in financial damage to the company.

**MDN**

**DATA EXCLUSIVITY**

**Of ALL INDUSTRIAL SEGMENTS THE PHARMACEUTICAL INDUSTRY BEING THE MOST R&D BASED INDUSTRY IS MOST CONCERNED ABOUT THE UNAUTHORISED APPROPRIATION BY OTHERS OF THE DATA GENERATED BY THEM AT HUGE COSTS AND EFFORTS OF SEVERAL YEARS.**

**THUS THIS INDUSTRIAL SEGMENT PLEADS FOR LEGAL PROTECTION OF DATA SUBMITTED TO REGULATORY AGENCIES FOR DRUG APPROVALS (DATA PROTECTION OR EXCLUSIVITY).**

**MDN**

**What Is Data Exclusivity ?**

**Data Exclusivity Laws typically provide that for a specified period the Regulatory Agencies should not part with or access the originator's data when considering a generic approval for a competitor. With such a provision, the generic drug manufacturer has to generate independent data on his product.**

**MDN**

**Interpretation of Art. 39.3 of TRIPS**

It has been contended in India that Art. 39.3 makes no mention of Data Exclusivity, only mentions Data Protection from unfair commercial use. The two are not the same as interpreted by U.S. & Japan.

Another suggestion is that the total period of exclusivity available for the originator of the data should not exceed the patent validity period so that additional protection in terms of time frame is not provided.

**MDN**

**How Important Is The Provision For Data Protection?**

- In normal cases the Data Exclusivity (DE) period will expire prior to the date of expiry of patent monopoly and hence DE has limited significance. However DE is not restricted to patented products.
- In addition, many countries have provision for extension of patent validity, eg., U.S., Australia, EU (Supplementary Protection Certificate) to compensate for delay in Drug approvals.

**MDN**

**Arguments In Favour Of Denying Provision For Data Protection**

The primary argument is that this is a strategy to evergreen exclusivity through yet another monopoly instrument. The present validity period for Patents under TRIPS is the longest ever granted in any country so far and is long enough to recoup the investments made in R&D.

Equally vehement is the argument that unwarranted repetition of data generation will add to the costs of the generic product, not to speak of the additional time required to generate the data. Delay in the introduction of the generic version will affect the patients' access to cheaper medicines.

This is particularly relevant to Developing Countries.

**Examples Of Data Protection Legislations**

**EU** ; 10 years from date of first approval in EC for EU registration and 6-10 years for national registration.

**New Zealand/ Australia** : 5 years.

**Japan** : 4 years for new indications, formulations etc.

6 years for NCEs and 10 years for orphan drugs.

**China** : 6 years from the marketing approval date.

**Laws For Protection Of Confidential Information- U.S.A.**

**Uniform Trade Secrets Act Of U.S.A.** – 40 States have adopted .

**Economic Espionage Act -1996** : Makes the theft or misappropriation of a Trade Secret a federal offence. The two provisions are : Under 18 USC ( 1831 a)- theft of trade secrets to benefit foreign powers criminalised; 18USC (1832) criminalises the theft for commercial and economic purposes

**Hatch-Waxman Act -1984** : Data Exclusivity for 5 years for New Drugs & 3 years for New Uses.

**A PROFILE OF THE INDIAN PHARMACEUTICAL INDUSTRY**

**HEALTH INFRASTRUCTURE**

Doctors	6,25,130 (0.58) *
Nurses	8,36,000 (0.77) *
Hospitals	16,000
Hospital Beds	8,70,000 (0.81)*
Primary Health Centres/ Community Health Centres	1,64,000
Medical Colleges	171
Chemists	5,00,000
Medical Reps	3,00,000

\* Per 1000 Population

**INDIAN PHARMA SCENARIO – 2004**

Domestic sales of Rs.27000 Crores. (U.S.\$ 6.7 Bio.)  
 Exports : Rs. 18300 Crores (U.S.\$ 4.4 Bio.)  
 No.1 Company (Domestic) – CIPLA  
 Sales Rs.11,28 Crores.  
 Market Share – 5.5%  
 Fastest growing segments – Anti-diabetics, Cardiovascular and CNS Drugs  
 Annual R&D spend ~ Rs.1200 Crores (\$ 270 mio)  
 4% of T.O

**INDIAN PHARMA INDUSTRY**

<p><b>STRENGTHS</b></p> <ul style="list-style-type: none"> <li>- Excellent Reverse Engineering Skills</li> <li>- Cost Competitiveness</li> <li>- Well Trained Technical Manpower</li> <li>- API Production Technology</li> <li>- Entrepreneurship</li> <li>- Well developed Ancilliary Industry</li> </ul>	<p><b>WEAKNESSES</b></p> <ul style="list-style-type: none"> <li>- Drug Discovery Skills</li> <li>- Marketing Strengths</li> <li>- Working in Isolation – Networking</li> <li>- Low Productivity</li> <li>- Lack of Focus</li> <li>- Low level of Resources</li> </ul>
--	---

**TOP 10 PHARMA COMPANIES - 2004**

Rank	Company	Sales* (Rs.Mn)	Market Share (%)
1	CIPLA	11285	5.5
2	GLAXO SMITH KLINE■	11143	5.4
3	RANBAXY	9190	4.5
4	NICHOLAS PIRAMAL	8720	4.3
5	SUN PHARMA	6738	3.3
6	PFIZER ■	5565	2.7
7	DR. REDDY'S	4988	2.4
8	ZYDUS-CADILA	4959	2.4
9	SANOFI-AVENTIS ■	4841	2.4
10	ARISTO	4760	2.3

\*Retail Sales; ■ MNC Affiliates Source: ORG IMS

**New R&D - Based Indian Pharma Companies**

The Top Ten Pharma Companies and a few others have seen the opportunity offered by the emerging IPR regime and have invested in New Drug Discovery Research. They Are : Ranbaxy, Dr. Reddys, Wockhardt, Torrent, Lupin, Zudus Cadila, Cadila Pharma, Nicholas Piramal, Glenmark, Aurobindo, Orchid. Many others are waiting on the wings.

They have made capital investments of 20 to 100 Crores and annually spend 20 to 400 Crores, primarily on New Drugs Research.

All of them are Patent - savvy and file large number of PCT, Indian & U.S Applications.

Their strategies are to do early discovery research, patent them and licence them for development to large foreign Companies. Over a Dozen INDs have been filed by these Companies.

**Schedule Y**

The Amended Schedule Y defines a 'New Drug' and specifies all requirements for it to be qualified for use in Humans. That includes norms for Clinical Trials, INDA, NDA, Generic Drugs etc.

Data Protection has significance in implementation of Schedule Y

**IPR KEY ISSUES IN INDIA:  
IS IPA 2005 TRIPS COMPLIANT ?**

- Compulsory Licensing Provisions, Implementation & Impact
- Patentability Criteria – Life Forms, Molecules
- Pre-grant & Post-grant Opposition
- Data Exclusivity (Data Protection of Confidential Information)
- Parallel Imports

With the advent of New Drug Research efforts by leading Indian Companies to cope with the Post-2005 era, we need to review our Regulatory Laws and bring in appropriate changes in them. And that includes provision for protection of Proprietary Data as well.

**CURRENT INDIAN SCENARIO**

The matter of granting Data Protection (Data Exclusivity ?) to the originator of the Data who has submitted it to the Regulatory Agency for obtaining the necessary approvals for Investigational New Drug (IND) use or for New Drug Application (NDA) is under the consideration of the Government and current indications are that India will follow most of the other countries and allow such protection with a few changes.

MDN

**In All These Matters We  
Need To Know What  
Direction to Take.**

*"I find the important thing in life is  
not so much where we stand, as  
in what direction we are moving".*

**Oliver Wendell Holmes**

MDN

**Alice:** " Which direction should I go? "

**Cat:** " It depends a great deal on  
where you want to go. "

*Lewis Carol in Alice in Wonderland*

MDN

**Alice:** " But I don't know where I want  
to go? "

**Cat:** " In that case, it really doesn't  
matter which direction you take."

**Lewis Carol in Alice in Wonderland**