Centre for CIPROM intellectual property management

NEWSLETTER

Volume No. 1 | Issue No. 9

September 2017

Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Policy
- Patent Law
- Copyright
- IP Valuation
- Technology Transfer
- Licensing
- Collaborations
- M & A
- Innovation Research
- Data Management
- Balance for Rights & Obligations

Editorial.....

A new "Draft Pharmaceutical Policy" has been recently announced and is being offered for debate and discussion. The Parent Ministries are hopefully "all ears" for possible suggestions and views for improving the "Health of the Nation, its people and the Indian Pharma Industry". While lamenting about erosion in indigenous production of APIs (Bulk Drugs), there is no concerted action to encourage or motivate or support indigenous production of APIs and building blocks. While there is IPA (Indian Pharmaceutical Association) to represent pharmacists in Pharma Industry, over the years, the Chemists, Chemical, Mechanical and Environmental Engineers, Clinicians and Pharmacologistsand allied professionals in Pharma Industry have been orphaned by the absence of any Professional Association to represent, organize, train or empower them. This is one of the major reasons in loss of interest and lack of empowerment in API production in the country. The role of Human Resources is often neglected in all the planning even if initiated. Another area affecting API production in the country is the problems faced in obtaining permissions from the MOEF (Ministry of Environmental and Forests) more specifically from the Central and State Pollution Control Boards (PCBs). While there are problems in getting approvals for New Drugs (new generic APIs) from CDSCO or State FDAs, there are no serious delays. The real delays are from MOEFs & PCB. From one side, the government is crying for more indigenous production of APIs and intermediates. On the other hand, no permission for expansion of capacities of even existing API plants, leave alone environmental clearances for new ones is being granted by the PCBs and MOEF. If an existing API manufacturer procures an order for a new API to be manufactured in India, he has to not only apply for "additional product" permission to be endorsed on his existing Drug Licence (which comes in reasonable time), he has to get permission from the PCBs & MOEF which takes between 1 to 2 years. By this time, the overseas client will find another supplier from another country, even if costlier. It is, therefore, imperative that the MOEF (and the PCBs under them) adopts a pragmatic approach. We strongly urge the MOEF and the State PCBs to allow expansion plans and new product introductions (1) after the unit applicant files the application and (2) initiate the expansion or launch the new product and (3) the MOEF/ PCB approves (or rejects) on ex-post-facto basis. The units opting for this route may provide to MOEF/PCBs an Affidavit in advance assuring to comply with the requirements/modifications imposed on the units ex-post-facto basis. This solution is especially feasible and practicable through advance RC (Responsible Care) certification through ACC (American Chemical Council). All RC certified API manufacturers could be given launch first and approve later option.

Unless the governments, ministries and departments concerned adopts a more pragmatic approach, no solutions to long-pending issues will come forth.

The same is the case with R&D in Pharma Industry. In earlier years, the CSIR institutes and academic research centres were flush with excellence in Human resource persons rich in R&D culture. Today, most of the CSIR centres (except few like NCL) are languishing and have very little of promise to offer to Industry. The much lauded hyper-rated NIPER (Mohali) has come out only as a virtual training centre with no R&D worth the name. Industry has to develop R&D on its own almost without exceptions. Industry-Academia

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collaborations (Public Private Partnership model) is being recommended. However, the Academia is almost devoid of high calibre research personnel, except in few institutions such as ICT (Institute of Chemical Technology, formerly known as UDCT), NCL (National Chemical Laboratory) and IISc (Indian Institute of Science). The pharma research in these institutes constitutes only one of the many streams, often miniscule. Industry need to have strong reciprocal knowledge generation initiatives to start with Academic research institutions. All these are possible only if Pharma Industry is left with creation of a corpus for R&D and not forced to bleed to death with excessive and random price controls. The over-reliance of the government on NGO based biased approach on drug pricing is virtually emptying the research surpluses in the pharma balance sheets. If the government is genuinely interested in pharma industry coming up with new molecules, the government must allow the industry to generate surpluses and earmark the funds for R&D in research corpuses which when retained and used for R&D, receives tax concessions or exemptions. As on date, there is more talk and less action. There is more tax, price cuts and obsession of "more profits in pharma". There is a need for more tax, more concessions or exemptions or retaining R&D corpuses in the Pharma Industry's coffers. If API and R&D has to succeed in India, the governments, ministries and departments concerned must change their mindsets and attitude to industry. Today Indian Pharma Industry is on the receiving end, the Draft Pharma Policy can be no exception.

BULLET COMMENTS ON DRAFT PHARMACEUTICAL POLICY

Positives	Negatives
• Preamble quotes private databases such as Pharma trac, AWACS, CMIE data etc. • Acknowledges fall in growth rate from 14.36% to 8.68%. • Notes that the sector employs about 2 million work force. • Acknowledges that no PSU contribution and is fully private enterprise driven. • Acknowledges achievements of Indian Pharma Industry. • Largest USFDA inspections, approvals (262), DMFs, ANDAs. • EDQM approves (253), WHO-GMP compliance (1300). Exports highest to USA (27%). Called "Pharmacy of the World". Renowned for high quality at competitive prices. • Fair & factual historical evaluation and need for a policy statement. • Needs to restore & revive API and KSM (other intermediates, key starting materials) indigenously. • Improve quality across the board. • Identifies delay in approval of a new drug and seeks to remedy the status. • Acknowledges lack of R&D • No new drug discovery • Key objectives spelt out. • Self-certification option for BA/BE compliance. • Innovation to be encouraged. • E-Pharmacy & generic sales to be encourages. • Database to be created jointly by DoP & CDSCO/DCGI. • Pricing policy to be defined. NPPA to only implement policy. • DPCO to move from price control to monitoring (NGOs will oppose).	• Statement in Para 3.14, "it is, therefore, an opportune moment to review their continuance and rationalise them" Whom? PSUs or private industry? • Policy initiatives for higher API and KSM manufacturing in India not clearly spelt out though the intention is laudable. More concrete solutions to be adopted. • Brand names in Pharma to be discouraged. • Loan licence/contract manufacturing to be discouraged. • Proposes interfering in marketing practices. • All NDDS to be certified as new drugs – This was included in earlier Drug Policy/DPCO also. But not treated as such by NPPA in earlier years. • No price control on Patented Drugs. • Overdependence and disproportionate involvement of NGOs and civil society groups in pricing by DoP, NPPA (and also through Health Ministry) need to be curtailed. Industry representation in committees prior to announcements required.

2ND WRCB INDUSTRY DAY

"From Lab to Bedside: Challenges and Opportunities in Converting Proof of Concept to Product" - The Wadhwani Research Center for Bioengineering (WRCB) will host its annual Industry Day

on Friday, September 8th, 2017

For details please follow the link to: http://www.iitb.ac.in/wrcb/en/event/2nd-wrcb-industry-day

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What to expect: Speeches and Panel discussions by industry leaders and networking opportunities.

Topics for Panel Discussion:

- Targeted and minimally invasive drug delivery.
- Biomedical devices and the new regulatory framework.
- Point of care and wearable diagnostics.

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Please follow the link below for registration and more details.

https://sites.google.com/view/wrcb-industryday2017

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Venue:

Victor Menezes Convention Centre (VMCC)

IIT Bombay, Powai, Mumbai

ISPE INDIA – ONE DAY TRAINING ON

"CONTAINMENT OF HIGH POTENT APIs IN API, OSD AND ASEPTIC PROCESSING WITH A FOCUS ON NEW EU REQUIREMENTS"[1]

HELD ON 27TH NOVEMBER, 2017.

VENUE

SciTech Center, 7 Prabhat Nagar,
Jogeshwari (West), Mumbai – 400102

To register and for more details please reach out to :

admin@ispeindia.org

[1] http://www.ispe.org/india-affiliate/27-nov-2017/containment-high-potent-api-flyer.pdf

INDO-GLOBAL SUMMIT & EXPO 2017
at Hotel The Lalit Mumbai

Industry
As
Facilitator-incubator
For Skill Generation And
Sourcing From Academia

Dr. Gopakumar G. Nair
Chairman
Gnanlex Hermeneutics Pvt. Ltd.
Indo-Global Summit & Expo
17th July, 2017

INNOVATION is the Key

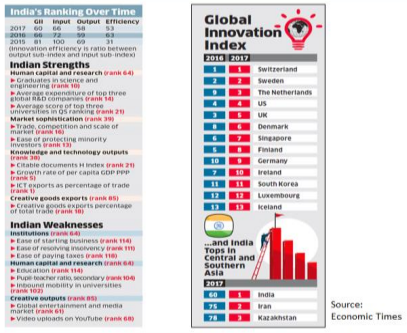
- Constitution of India – Fundamental Duties include

It shall be the duty of every citizen of India To develop the SCIENTIFIC TEMPER, humanism and the SPIRIT OF INQUIRY…

INNOVATION is the Platform and the Bridge

Industry with Academia

Need to make Strides in Innovation



Educational Curriculum

Should provide

Pride Of Place

for

INNOVATION – Creative Action

Venture Center - Model

Entrepreneurship Development Center (Pune)

Business Incubator focusing on technology commercialization via spin-offs/spinouts while nurturing startups in India.

The Model Could be adapted / adopted for Industry – Academia Partnership

http://www.venturecenter.co.in/

- **Industry Chair ----- In Academia**
- **Academia Chair ----- In Industry**

university industry

- **Technology Transfer & Licensing Centre in Universities / Academia**
- **Interns/Trainees ----- In Industry**