

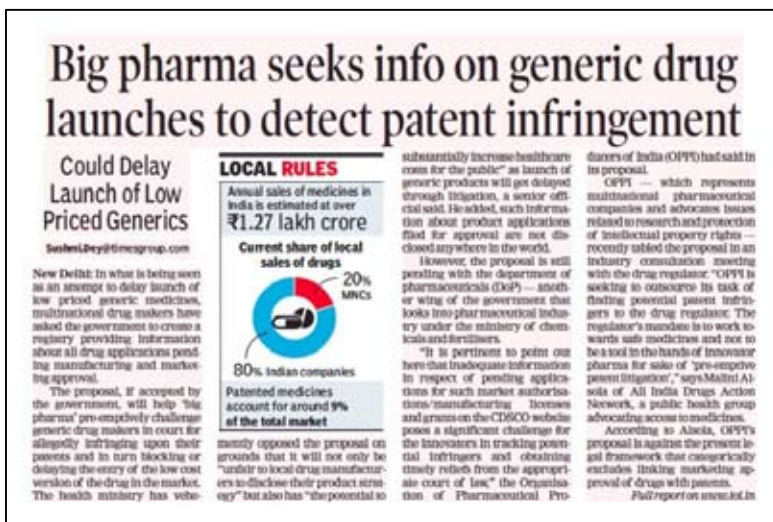
Intellectual Property advocacy in the fields of:

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



## Editorial...

Big Pharma, in a recent newspaper report (see insert), threatens Indian generic industry with infringement litigation with *ex parte* injunction if any Indian Pharma company applies for regulatory approval for a generic version of Innovator drug, for launch after expiry of the Indian Patent. Sec 107A(a) of Patents Act, 1970 specifically excludes manufacture and offering to third party in India or overseas, any patented drug in India, for R&D based trials leading to regulatory submissions. There have been numerous attempts in the past to file infringement suits to block regulatory approval to generic companies.



**Big pharma seeks info on generic drug launches to detect patent infringement**

**Could Delay Launch of Low Priced Generics**

**LOCAL RULES**

Annual sales of medicines in India is estimated at over ₹1.27 lakh crore

Current share of local sales of drugs

|                      |
|----------------------|
| 20% MNCs             |
| 80% Indian companies |

Patented medicines account for around 9% of the total market

*Substantially increase health care for the public" as launch of generic products will get delayed through litigation, a senior official said. He added, such information about product applications filed for approval are not disclosed anywhere in the world.*

*However, the proposal is still pending with the department of pharmaceuticals (DoP) — another wing of the government that looks into pharmaceutical industry under the ministry of chemicals and fertilizers.*

*"It is pertinent to point out here that inadequate information in respect of pending applications for such market authorizations/manufacturing licenses and grants on the CDSCO website poses a significant challenge for the innovators in tracking potential infringers and obtaining timely relief from the appropriate court of law" the Organisation of Pharmaceutical Pro-*

*ducers of India (OPPI) had said in its proposal.*

*OPPI — which represents multinational pharmaceutical companies and advocates issues related to research and protection of intellectual property rights — recently tabled the proposal. In an industry consultation meeting with the drug regulator "OPPI is seeking to outsource its task of finding potential patent infringers to the drug regulator. The regulator's mandate is to work towards safe medicines and not to be a tool in the hands of innovator pharma for sale of "pre-emptive patent litigation"; says Madhuri Ahluwalia of All India Drugs Action Network, a public health group advocating access to medicines.*

*According to Ahluwalia, OPPI's proposal is against the present legal framework that categorically excludes linking marketing approval of drugs with patents.*

*PhD/report on innovation in*

.....Contd on pg 3

CIPROM has pleasure to congratulate Dr. Yusuf Hamied, Chairman, CIPLA on his being awarded **"Honorary Fellow of the Royal Society"** in April 2019, for his exceptional contributions to science. Dr. Hamied has also been felicitated by Department of Chemistry, University of Cambridge, being a distinguished Alumnus of Cambridge University. The Chemistry Department at Cambridge has also named "Todd-Hamied Meeting Room" in honour of Prof. Todd & Dr. Yusuf Hamied. Most recently, the Chemistry Chair of University of Cambridge has been renamed as "Yusuf Hamied 1702 Chair of Chemistry".



The links to the announcement of the Awards are as follows:

<https://royalsociety.org/news/2019/04/royal-society-announces-2019-fellows/> and <https://www.ch.cam.ac.uk/news/distinguished-alumnus-elected-honorary-fellow-royal-society>

**CIPROM extends Heartiest Congratulations to Dr. Yusuf Hamied.**

## INDIAN DRUGS ANNUAL DAY 2019



*Snapshots from the Indian Drugs Annual Day held on 22<sup>nd</sup> March 2019 at IES, Mumbai.*

*Dr. Ahmed Kamal (Pro Vice Chancellor Jamia Hamdard University), Dr. Mrs. Madhu Dikshit (ex CDRI Director) and Dr. V Premnath (Head, NCL Pune) were the Guests of honour on the occasion. IES, Bandra actively participated and hosted this program of "Indian Drugs", IDMA.*







## **NEW (10<sup>th</sup>) BATCH OF PATENT GURUKUL® STARTED ON 7<sup>th</sup> APRIL**

10th Batch of GNA Patent Gurukul® commenced on 7th April 2019 at the Conference Room of GNAs at Akurli Road, Kandivali East, Mumbai- 400101. Patent Gurukul has, over the years, empowered many students and industry professionals on IPR/ Patent Law and Practice. We are proud that Gurukul alumni are spread all over the world and also in Indian corporates, research and professional practice.



### **INDIA MARKS HIGHEST GROWTH IN FILING FOR INTERNATIONAL PATENTS**

India has filed more than two thousand international patent applications, thereby marking the highest growth among the top 15 nations. According to data from the global intellectual property (IP) services of the World

"Asia is now the majority filer of international patent applications via WIPO, which is an important milestone for that economically dynamic region and underscores the historical geographical shift of innovative activity from West to East."

— Director General Francis Gurry

Intellectual Property Organisation, 2018 innovators from Asia have filed over 50% of international patents. India marked a significant growth of 27%. A closer look at Indian patents show that most of these have been filed by TVS Motor Company ranking first, the Council of Scientific and Industrial Research and the Indian Institute of Technology ranking second and Reliance Industries at a close third.

<https://www.financialexpress.com/lifestyle/science/innovation-by-indians-growing-india-marks-highest-growth-in-filing-for-international-patents/1530507/>

#### ***Editorial .....Contdfrom pg 1***

There have also been judgements from High Courts and Supreme Court, upholding the validity of Sec 107A(a) and refusing to grant ex parte injunction, in recent times. As such, the recent news report indicates an attempt to revive the aggressive litigation for preventive (ex parte) injunctions against grant of regulatory generic product approvals. The Office of the DCGI/ CDSCO is often the target of such injunctive approaches. India has not legislated on or granted "drug exclusivity" or regulatory data protection. Further, (Indian) Patents Act, 1970, has exemptions under Sec 107A(a) and Section 47(3) for research and regulatory approval. Excessive and preventive litigation and infringement suits are being pursued by MNCs, to frustrate generic manufacturers, especially since Indian generic industry cannot afford expensive defensive litigation expenses. If this aggressive approach continues, Indian generic pharmaceutical industry should approach the Government to treat Pharma patents in India as Standard Essential Patents (SEPs) which need to be licensed on FRAND (Fair, Reasonable and Non-Discriminatory) terms. This will facilitate liberal non-exclusive licensing and make the royalties affordable to generic companies. Encouragement and enforcement of liberal licensing for Pharma Patents and products similar to electronics and other fields of technology will ensure affordability, availability and accessibility to life saving medications.

## NEWS SNIPPETS

### Prices of 390 non-scheduled cancer medicines slashed by up to 87 per cent

The National Pharmaceutical Pricing Authority (NPPA) on February 27 had brought 42 non-scheduled anti-cancer drugs under price control, capping trade margin at 30 per cent.

[https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/prices-of-390-non-scheduled-cancer-medicines-slashed-by-up-to-87-per-cent/articleshow/68322659.cms?utm\\_source=ETTopNews&utm\\_medium=Social&utm\\_campaign=ETFBMain&utm\\_content=23%3Futm\\_source%3Dfacebook.com&fbclid=IwAR1VuWFy4Hbu-Ce-Kv\\_KCeclu2goEzINTzorMiMm5arAJwHolseOD0\\_3GTs&from=mdr&utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/prices-of-390-non-scheduled-cancer-medicines-slashed-by-up-to-87-per-cent/articleshow/68322659.cms?utm_source=ETTopNews&utm_medium=Social&utm_campaign=ETFBMain&utm_content=23%3Futm_source%3Dfacebook.com&fbclid=IwAR1VuWFy4Hbu-Ce-Kv_KCeclu2goEzINTzorMiMm5arAJwHolseOD0_3GTs&from=mdr&utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)

### Peru, Chile set to slug it out in Indian courts over 'Pisco' brandy GI tag

South American nations Peru and Chile may end up in Indian courts as both have locked horns in the country over GI (Geographical Indications) tag on 'Pisco' brandy.

[https://www.business-standard.com/article/companies/peru-chile-set-to-slug-it-out-in-indian-courts-over-pisco-brandy-gi-tag-119031000188\\_1.html](https://www.business-standard.com/article/companies/peru-chile-set-to-slug-it-out-in-indian-courts-over-pisco-brandy-gi-tag-119031000188_1.html)

### Claims are Invalid (not Patents)

The two-paragraph decision in this case is designed to serve as a reminder that patent validity/infringement is considered on a claim-by-claim basis.

<https://patentlyo.com/patent/2019/03/claims-invalid-patents.html>

### Fill up vacancies in important tribunals in 14 days, orders SC

Taking note of tribunals being starved of manpower and infrastructure for years, the Supreme Court on Wednesday expressed concern over the large number of vacancies in important tribunals and asked the Centre to fill them up in two weeks.

<https://timesofindia.indiatimes.com/india/fill-up-vacancies-in-important-tribunals-in-14-days-orders-sc/articleshowprint/68606001.cms>

## IPR lecture in ICT

Dr. Gopakumar g. Nair, CEO, Patent gurukul, was invited to ICT (Institute of Chemical Technology), the most distinguished Institute at Mumbai on Chemical Technology and Pharmaceuticals among other subjects. ICT is in the forefront of innovation. Illustrious industry and Research luminaries such as Padmavibhushan Dr. R. A. Mashelkar, Padmavibhushan Professor M.M. Sharma, Mr. Mukesh Ambani and others make ICT a proud Indian Technology incubator.

