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#### **1 Day Seminar on Current Themes in Pharma Patenting** - Organized by IPFACE, Venture Center & IP Group, NCL Innovations -Overview and insights on recent developments in Patent Law and practice of relevance to the pharma industry and research including: • Case studies on exclusion categories in the Indian Patent Law Strategies that MNCs are following if they do not get their patent granted • **LEARN** • Compulsory Licensing • National IPR Policy Indian Scenario and International Scenario on Pharma Patenting • IP Facilitation center (IPFACE), Venture Center • Intellectual Property Group, NCL Innovations, CSIR-NCL **ORGANIZED BY** Gnanlex Hermeneutics; Gopakumar Nair Associates Venture Center • SUPPORTED BY Biotechnology Industry Research and Assistance Council (BIRAC), Govt. of India via the **Biotech Ignition Grant Mentoring Programme** Research/ Science Managers/ CTOs/ CSOs in Research/ Technology Organizations/ • Companies Technology/IP Managers/Patent Professionals/ Innovation Officers FOR WHOM • Students of IPR, Patent Law, Other law disciplines, Pharma/ Biotech • Inventors Saturday, 20th June 2015 | Time: 9:00 AM- 5:30 PM WHEN Ashutosh Prachand **IPFACE LEAD** E-Classroom, Venture Center, 100 NCL Innovation Park, WHERE Dr. Homi Bhabha (Pashan) Road, Pune-411008 Ms. Lipika Biswas | Phone: +91-20-25865877 | Email: eventsdesk@venturecenter.co.in CONTACT Category Fees Medium and large companies 3,500/-2,500/-Individual/ Micro and Small Enterprises Academic Institutions/Non-profit Organizations 1.500/-Limited seats: 30 COST Register here: http://www.ipface.org/workshops.php Note:-Fees paid is not refundable and non transferable under any circumstances. Organizers reserve the right to select participants so as to maximize learning and networking opportunities for the group





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# Introduction

Intellectual property rights (IPR) in the pharma domain have been a argumentative issue globally. Previously, the IPR debates were typically between the branded pharma companies and generic pharma companies. India was no exception to this IPR battle and in view of the large poor population in need of its basic healthcare; the Indian authorities were initially not keen on granting substantial IPR protection. However, over a period of time, the Indian authorities have become more sensitized to the need and importance of IPR protection for the long-term good of industry.

The aim of the seminar is to have an overview of the key aspects and trends in pharmaceutical industry in view of the recent decisions and policy making for the protection of Intellectual Property and also tapping on international Intellectual property protection scenario in light of the USPTO guidelines on natural products, shift in business decision making and adequate exploitation of patent rights and how MNC's develop an IP strategy for their business and seek to integrate it within their overall business strategy.

### **Course Outline**

- Overview and introduction to pharma patenting. Key aspects of the patent law with respect to pharma industry and research. Overview of trends and current themes in pharma patenting
- Indian scenario:
  - o Recent case studies relating exclusion categories in the Indian Patent Law
  - o Guidelines for examination of patent applications in the field of Pharmaceuticals
  - Compulsory licensing
  - o National IP Policy and its implications
- International scenario:
  - o Patentable subject matter at USPTO: Implications for Pharma and Healthcare Industries-
  - Recent FDA decisions on regulatory exclusivities: Rationale and Implications
  - o Sovaldi (Gilead)
  - What are the strategies that MNCs are following if they do not get their patent granted?
  - Settlements in drug patent litigation

## **Course includes**

- Certification of Participation
- Access to restricted website with online compilation of resources
- Course includes tea and lunch at Venture Center cafeteria
- Free one-year reference membership for Venture Center Library









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015       Lipika, Ashutosh         000-0930       Registration       Lipika, Ashutosh         030-1000       Introduction to the workshop       N S Tewari         000-1100       Session 1: Introduction and overview of current trends and themes (60 min)       Gopakumar Nair         100-1115       Tea break       Session 2: Selected Indian themes       Andreya Fernando         •       Recent case studies relating exclusion categories in the Indian Patent Law (20 min)       Andreya Fernando	E-Classroom E-Classroom Foyer area des
030-1000       Introduction to the workshop       N S Tewari         000-1100       Session 1: Introduction and overview of current trends and themes (60 min)       Gopakumar Nair         100 - 1115       Tea break       Session 2: Selected Indian themes         •       Recent case studies relating exclusion categories in the Indian Patent Law (20 min)       Andreya Fernand	E-Classroom E-Classroom Foyer area des
OOD-1100       Session 1: Introduction and overview of current trends and themes (60 min)       Gopakumar Nair         100 - 1115       Tea break       Session 2: Selected Indian themes       Andreya Fernand         •       Recent case studies relating exclusion categories in the Indian Patent Law (20 min)       Andreya Fernand	E-Classroom Foyer area
100-1100       and themes (60 min)       Gopakumar Nair         100 - 1115       Tea break       Session 2: Selected Indian themes         •       Recent case studies relating exclusion categories in the Indian Patent Law (20 min)       Andreya Fernand	Foyer area
<ul> <li>Session 2: Selected Indian themes</li> <li>Recent case studies relating exclusion categories in the Indian Patent Law (20 min)</li> </ul>	les
Recent case studies relating exclusion categories in the Indian Patent Law (20 min)	
<ul> <li>Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (45 min)</li> <li>Compulsory licensing (20 min)</li> <li>National IP Policy and its implications (20 min)</li> </ul>	E-Classroom
300–1345 Lunch break	Cafeteria
Session 3: Selected International themesM G Kulkarni• Recent FDA decisions on regulatory exclusivities: Rationale and Implications (45 min)M G Kulkarni• Patentable subject matter at USPTO: Implications for Pharma and Healthcare Industries (45 min)Durgesh Mukhar• What are the strategies that MNC's are following if they do not get their patents granted and settlements in drug patent litigation (30 min)Anup Ranade• Sovaldi Case Study (30 min)Andreya Fernance	des
515–1630         Networking tea break and Group Photograph	Foyer area
Session 4: Panel discussion and Q&A       Panelists: M G Kulkarni Durgesh Mukhar Gopakumar Nair Anup Ranade N S Tewari Premnath Venug         530-1730       Moderator: Srividya Ravi	E-Classroom
730–1745 Q&A, Feedback & Closure IPFACE Team	E-Classroom









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Speakers (in alphabetical order of last names)		
Andreya Fernandes	Registered Patent and Trademarks Agent Master Degree in LLM (IPR), SNDT University, LLB (Law), Mumbai University, Bachelor Degree in Microbiology and Biochemistry, Mumbai University. Working with Gopakumar Nair Associates as IP/Patent and Legal Associate	
MG Kulkarni	<ul> <li>Ph D(Chemistry) - Year: 1950, Mumbai University</li> <li>Dr. Kulkarni area of interest is in controlled release delivery systems, molecularly imprinted polymers, Protein Carbohydrate interactions, Supramolecular Chemistry of Polymers, R&amp;D Management. He has been awarded Young Associateship of the Indian Academy of Sciences, Bangalore (1984), Fellow of the Maharashtra Academy of Sciences (1990), Fellow of the Indian Academy of Sciences, Bangalore (1984), Fellow of the Maharashtra Academy of Sciences (1990), Fellow of the Indian Academy of Sciences, Bangalore (1984), Fellow of Sciences, Bangalore (1996), Indian Society for Plastics Pune, award for research in Polymers (1996), IPI-UDCT Diamond Jubilee Visiting Professor in Polymer Processing (1997), KG Naik Gold medal 1999</li> <li>Senior Associate at K&amp;S Partners</li> </ul>	
<b>Durgesh Mukharya</b>	One of the Team leaders for Life Science team in Bangalore Office of the firm. He handles patent drafting and prosecution including oppositions in the areas of biotechnology, microbiology, bioinformatics, bio-pharmaceuticals, genetic engineering, medical diagnostics, therapeutics and biochemistry. He also advises clients on issues related to patentability, freedom to operate, due diligence and technology landscape besides managing patent portfolios and conducting patent workshops. He regularly appears before the Indian Patent Office and the Intellectual Property Appellate Board in connection with prosecution of patent applications and related matters. Durgesh is also regular speaker at various conferences and seminars.	
Gopakumar Nair	Founder, Gopakumar Nair Associates Dr. Gopakumat Nair has 40 years of experience and knowledge in pharmaceutical and chemical industry at different levels and positions like Director, Chairman & Managing Director, as well as Past-President of Indian Drug Manufacturers' Association, Dr.Gopakumar G. Nair had opportunity to familiarize himself with GATT, WTO, TRIPs and other IP laws over the years. With this wealth of experience Dr. Nair became an IP/Patent practitioner under the name Gopakumar Nair Associates.	
Ashutosh Prachand	Jr. IP Associate, IP Facilitation Center at Venture Center He has completed PG Diploma in Patents Law, NALSAR University, prior to that he pursued PGDM Biotechnology Management and has a bachelor's degree in Biotechnology from University of Pune.	









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Srividya Ravi	<ul> <li>I/C Gnanlex (Patent attorney Firm by Dr. Gopakumar Nair), office in Pune, Patent associate in NCL.</li> <li>Patent drafting &amp; prosecution</li> <li>Post graduate Diploma in Patent Law from NALSAR, Registered Patent Agent</li> <li>Master of Pharmaceutical Sciences from SNDT, Mumbai, Trained form AOTS, Japan of techniques involved in "Company-Wide Problem Solving" in 1996</li> </ul>
Anup Ranade	Associate Director, Patents, Advinus Therapeutics LLB, Pune University; Ph.D. Synthetic Organic Chemistry, Pune University; PG Diploma in Patents Law, NALSAR He is currently heading the Patents Department at Advinus Therapeutics. His areas of activity involve Novelty/patentability evaluations, FTO opinion, Patent drafting strategies, Prosecuting patent applications. Training/creating awareness among the teams on the various Intellectual property related matters. His specialty includes competitive analysis, Budgeting as well as managing the Intellectual Property Management costs
	Assistant Controller of Patents & Designs CGPDTM, Mumbai
Amarendra Samal	Dr. Samal has a Ph. D. in Chemistry in the year 2000 and then worked as post doctorate fellow (R.A.) in National Metallurgical Laboratory from the year 2000 to 2002. In 2002 (August) I joined in Patent office as examiner of Patents and Designs and elevated to the post of Assistant Controller in 2009. Basic work discharging now is supervising the work of examiners of Patents in the field of Chemistry and pharmaceutical fields which includes search, examination and grant of Patent applications in the said field as per the statutory provisions.
9	Scientist, IP Group / NCL Innovations         Patent drafting & prosecution, IP portfolio planning, management and value addition         PhD (Biomed Research), WoS-C fellow of DST, Registered Patent Agent
Nitin Tewari	









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About the Organizors	
About the Organizers	IPFACE aims to promote awareness and adoption of intellectual property rights amongst entrepreneurs and MSMEs in India while also making accessible high- quality IP services and resources. IPFACE is a project of the Venture Center supported by the Ministry of Micro, Small and Medium Enterprises, Government of India and National Chemical Laboratory, Council of Scientific and Industrial
INCLUSION Bindian from CSE bola	Research, India. For more information about IPFACE services, visit www.ipface.org The National Chemical Laboratory, India is a research, development and consulting organization with focus on chemistry and chemical engineering. It has a successful record of research partnership with industry. NCL Innovations is resource center of NCL that supports, promotes and champions the cause of technology innovations within NCL. For more information about NCL Innovations & IP group NCL, visit http://www.nclinnovations.org/
GNA'N'Lex Hermeneutics Pot, Ltd.	GNANLex Hermenueticus Pvt. Ltd is a Knowledge & Technology based firm providing services in Intellectual Property, regulatory linkages, technology development, licensing & contracts of IP related areas within India and globally. Currently located in Mumbai, GNANLex Hermenueticus Pvt. Ltd is serving the IP needs of Pune by providing services to various organizations in and around Pune For more information, visit: <u>http://www.gnanlex.com/</u>
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	Entrepreneurship Development Center (Venture Center) – a CSIR initiative – is a Section 25 company hosted by the National Chemical Laboratory, Pune. Venture Center strives to nucleate and nurture technology and knowledge-based enterprises by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator

by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB). Venture Center's focuses on technology enterprises offering products and services exploiting scientific expertise in the areas of materials, chemicals and biological sciences & engineering. For more information, visit www.venturecenter.co.in
 Biotechnology Industry Research & Assistance Council is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be

interface and implements its mandate through a wide range of **impact initiatives**, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring **innovation excellence** to the biotech firms and make them globally competitive. For more information about BIRAC: www.birac.nic.in

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