



INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed Edition :

www.ijlra.com

DISCLAIMER

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Managing Editor of IJLRA. The views expressed in this publication are purely personal opinions of the authors and do not reflect the views of the Editorial Team of IJLRA.

Though every effort has been made to ensure that the information in Volume 2 Issue 7 is accurate and appropriately cited/referenced, neither the Editorial Board nor IJLRA shall be held liable or responsible in any manner whatsoever for any consequences for any action taken by anyone on the basis of information in the Journal.

Copyright © International Journal for Legal Research & Analysis

IJLRA

EDITORIAL TEAM

EDITORS



Megha Middha

Megha Middha, Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar

Megha Middha, is working as an Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar (Rajasthan). She has an experience in the teaching of almost 3 years. She has completed her graduation in BBA LL.B (H) from Amity University, Rajasthan (Gold Medalist) and did her post-graduation (LL.M in Business Laws) from NLSIU, Bengaluru. Currently, she is enrolled in a Ph.D. course in the Department of Law at Mohanlal Sukhadia University, Udaipur (Rajasthan). She wishes to excel in academics and research and contribute as much as she can to society. Through her interactions with the students, she tries to inculcate a sense of deep thinking power in her students and enlighten and guide them to the fact how they can bring a change to the society

Dr. Samrat Datta

Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board



Dr. Namita Jain



Head & Associate Professor

School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC -NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.

Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India. India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time & Utkrisht Bharat Foundation, New Delhi.(2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020). Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019

Mrs.S.Kalpana

Assistant professor of Law

Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr. Sagunthala R & D Institute of Science and Technology, Avadi. Formerly Assistant professor of Law, Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr.Ambedkar Law College, Pudupakkam. Published one book. Published 8 Articles in various reputed Law Journals. Conducted 1 Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration. 10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.



Avinash Kumar



Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship. He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi. Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi. He has qualified UGC - NET examination and has been awarded ICSSR - Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS
ISSN

2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

PATENT WARS IN THE PHARMACEUTICAL INDUSTRY: BALANCING ACCESS TO MEDICINE AND INNOVATION

AUTHORED BY - NEHA SHARMA & DR SUPERNA VENAİK
LLB (3YR), 6TH SEM
AMITY LAW SCHOOL
AMITY UNIVERSITY, NOIDA

ACKNOWLEDGMENT

I owe a sincere thank you to everyone who gave me assistance and encouragement when I was writing my research paper. They all had trust in me and provided me with direct or indirect support as I conducted the necessary research and study. I want to thank Amity University in Noida, Uttar Pradesh, for giving me groundwork and a chance to be a member of the university. I want to firstly express my profound appreciation to my mentor Dr Superna Venaik ma'am for her unwavering support of my research paper throughout study and research, as well as for his patience, inspiration, excitement, and vast expertise. His advice was helpful to me throughout the whole research and writing process for this book. Last, but certainly not least, I would like to express my sincere gratitude to my family and friends for their unwavering encouragement throughout my life.

INTRODUCTION

India and the Patent Wars examines struggles over patents and medical access among pharmaceutical producers, activists, and others under a new global intellectual property regime. India, one of the world's largest pharmaceutical exporters, has been at the center of these struggles. This book explores multiple perspectives on these controversies including those of Indian pharmaceutical companies, which have long offered low-cost medicines to customers around the world, multinational pharmaceutical companies, which pursue patent claims in Indian courts and license drugs to Indian producers, and practitioners of ayurveda, India's largest indigenous medical system, who are concerned about how their knowledge and practices relate to the new patent system.

The introduction opens with a discussion of the current state of intellectual property law which has been greatly expanded around the world at the behest of corporate interests and the World Trade Organization, imposing limitations on the sharing of medical, scientific, and artistic creations. A brief discussion of India's large pharmaceutical sector and multinational big pharma is presented followed by a depiction of the practice of ayurvedic medicine in India and concerns about biopiracy, or the commercial exploitation of indigenous medical knowledge. The introduction also offers a discussion of problems of resistance and the intelligibility of power in a complex global system such as the new patent regime and cautions against simplistic depictions of an all-powerful "big pharma" in analyzing the global economy of pharmaceutical production.

THE INVENTION AND EXPANSION OF INTELLECTUAL PROPERTY

This chapter depicts the emergence of the concept of intellectual property starting with analyses of intangible property in pre-capitalist societies and the development of patents and copyrights in 15th-18th century Europe. Court decisions that expanded the scope of intellectual property in the last few decades in the U.S. are presented followed by a review of the development of patent treaties from the Paris Convention of 1883 to the current World Trade Organization TRIPS legislation which required a rewriting of patent laws in India and around the world. India's 1970 Patents Act, the reigning law until the TRIPS regime, prohibited product patents on medications, allowing only patents on the process of making a drug to prevent monopoly control of medications. In 2005, India had to change its law to comply with the WTO by allowing product patents and exclusive market control of medications.

THE NEW PATENT REGIME

This chapter examines efforts to resist the implementation of the new patent regime in India out of concern for the price of essential medicines. The Indian pharmaceutical sector has been a principal source of low-cost medicines for developing countries, but may no longer be able to produce inexpensive copies of medications patented elsewhere. India's WTO-compliant patent law has a silver lining, however, since it requires companies to demonstrate increased effectiveness of new drugs over the standard of care, provisions against "evergreening" of patents that are not required by US patent laws. Activists in India have been able to defeat several recent patent applications under this provision. The pharmaceutical giant Novartis challenged this provision in the Indian Supreme Court while at the same time, the company was holding patents

for medical products that were derived from India's indigenous Ayurvedic medical system.

AYURVEDIC DILLEMAS-INNOVATION & OWNERSHIP

The chapter opens with the history of the sharing and stealing of biological knowledge between India and the West including the story of how the drug reserpine made its way from practitioners of ayurvedic medicine to Novartis' patent portfolio. The chapter then moves to a discussion of how Ayurvedic medicine fits and does not fit, the requirements of patent law using the perspectives of Ayurvedic practitioners and manufacturers I interviewed. Modern patent law leaves Ayurvedic medical knowledge unprotected because Ayurvedic doctors use plant materials and do not isolate active chemical ingredients that may exist in these materials and also because Ayurvedic practice is believed to be communal and traditional and not based on individual invention. I also show how ayurvedic doctors and producers of ayurvedic pharmaceuticals have developed diverse responses to the new regime including efforts to create proprietary ayurvedic drugs and compile their knowledge in a digital library.

THE GILEAD MODEL AND THE PERSPECTIVE OF BIG PHARMA

Here this study takes into account the perspective of multinational pharmaceutical companies. I first discuss the difficulties I encountered in getting access to individuals from pharmaceutical companies who would speak on patent issues and how I was eventually able to speak with representatives from Gilead and Pfizer. Gilead Sciences, a mid-size US-based company, is voluntarily allowing 16 Indian generic pharmaceutical producers to manufacture their drug, tenofovir, a crucial WHO-recommended therapy for HIV/AIDS. As a result, the price of tenofovir has gone down dramatically. This chapter assesses the meaning of these events and argues that the priority of pharmaceutical companies under the new patent regime is not to get people in poor countries to start paying high drug prices but to protect their markets in wealthy and middle-income countries. The real problem of access under the new patent regime may turn out to be for the poor who live in middle-income countries.

THE “INDIAN” PHARMACEUTICAL INDUSTRY AND THE NEW PATENT REGIME

The boom town of Hyderabad is the center of India’s pharmaceutical industry, and this was where I met with representatives from two Indian pharmaceutical companies to discuss topics such as economies of scale in pharmaceutical production—the special capacity of the Indian pharma sector licenses with foreign multinationals such as Gilead and prospects for new research and development. This chapter argues that those who anticipate a simple takeover by “multinational” companies of “Indian” companies, which are also multinational, simplify what are complex and surprising emergences negotiated by quite powerful India-based corporate actors. The chapter also examines the first two patented drugs developed in India under the new patent regime, an anti-malarial medication and a cancer drug, and considers whether new research by Indian companies will focus on medical problems affecting low-income countries or on products for high-income markets.

CONCLUSION

The conclusion reiterates the problems with analyzing this new constellation of power and predicting its outcomes. Certain effective provisions are highlighted such as Section 3d of India’s new Patents Act which maintains rigorous standards of inventiveness and efficacy, preventing the “evergreening” of patents and “me too” drugs that have been awarded patents elsewhere. The study ends with a brief comparison to similar patent struggles in Brazil and an assessment of programs that offer more equitable approaches to innovation and ownership such as the Health Impact Fund and the Open-Source Drug Discovery program.