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## Patenting in India –balancing access to affordable medicines and patents for pharmaceutical innovators

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The issue of intellectual property and in particular patents is a matter of debate. The issue is more important with respect to pharmaceutical patents and various stakeholders which have led to fierce policy debate regarding patenting across the globe and in developing countries in particular. It is argued that patients in developing countries are deprived of access to health as newer medicines under patent are out of reach of millions either due to lack of access or due to prohibitive costs. The flexibilities under Trade Related Aspects of Intellectual Property Rights (TRIPS) are granted to member countries in order to protect public health. One of the flexibilities is granting compulsory license. Various developing countries such as Thailand granted compulsory license in the past in order to protect public health, but till recently India did not use the flexibility of compulsory license. The recent issue of compulsory license in India for Bayer's anti-cancer drug Nexavar (Sorefenib Tosylate), has opened a pandora's box. Since, multinational pharmaceutical companies may fear to introduce newer medical therapies in Indian market, it is important to repose their faith in the system so that new medicines are launched in India. Various measures such as monitoring of prices of patented medicines, negotiating the price of a patented medicine by the government before marketing, providing petty patents (utility patents) for minor innovations, procurement of patented medicines by government for public distribution, encouraging healthcare insurance, fostering Industry-Institute partnerships etc. may help balance access to affordable medicines and incentive for innovators.

### Biography

Manthan D Janodia has completed PhD in Intellectual Property Rights from Manipal University, Manipal in 2009. He is currently working as Assistant Professor in Department of Pharmacy Management, MCOPS, Manipal. He has published research and review articles in national and international journals. He has contributed chapters in book. He has presented papers in various national and international conferences on the topic of Intellectual Property. He is recipient of AICTE travel grant. He is a life member of APTI. He is also reviewer for various journals and is editorial board member of Journal of YoungPharmacists.

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## New drug screening strategy for chronic infectious diseases: The power of common sense

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The new challenge faced by the pharmaceutical industry is the development of treatments for chronic diseases combining genetic and environmental factors. Unfortunately, old habits die hard, as most companies still use *in vitro* drug screening models only reproducing the genetic defects. This presentation provides evidence for the urgent need to develop *in vitro* models accounting for the genetic and environmental factors to improve clinical trial success. For example, cystic fibrosis (CF) is a genetically-inherited disease which predisposes the patients to chronic airway obstruction and infection. The capacity of a compound delivered by inhalation to improve airway clearance is routinely tested on aseptic cultures of human airway epithelial cells from CF patients. While this high-throughput technique identifies many well tolerated drugs, most of them fail to improve clearance in CF patients. We recently developed a new *in vitro* model of CF airway disease that incorporates chronic infection. Primary cultures of epithelial cells from CF patients exposed > 3 days to CF sputum developed characteristics that close reproduce the disease, as shown by tissue immunolocalization. The infection caused extensive remodeling of the epithelial barrier lining the airway walls and a polarity shift for several surface proteins, including potential drug targets. This study illustrates the tremendous potential of this new approach to improve the stringency of drug screening, and the success of clinical trials for chronic infectious diseases. This complete *in vitro* model would "kill" inefficient candidates early in the pipeline, before they enter complex animal protocols and "metabolites in safety testing" (MIST).

### Biography

Picher is a medical research scientist specialized in drug development for respiratory diseases, with 14 years of experience in drug discovery. As principal investigator at the Cystic Fibrosis/ Pulmonary Research and Treatment Center (NC), she discovered a new signaling pathway regulating airway clearance, currently targeted by Biotech/Pharma. As independent consultant expert for CFRx and Flatley Venture Capital (FVC), she currently provides advices on *in vitro* models and drug screening protocols, and evaluates the scientific soundness of drugs selected for clinical trials by companies soliciting partnership with FVC. Dr. Picher published 75 scientific documents and is editor-in-chief of a book on drug discovery (Springer, 2011).

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