Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Patents in Indian pharmaceutical industry: Legal and ethical issues

B. S. Kuchekar
MAEER's Maharashtra Institute of Pharmacy, India

In the post-independence era, the Indian pharma market was completely dominated by multinational companies (MNCs) and most of the medicines were imported in India. The cost of medicines in India was among the highest in the world. In 1970, Indian Patents Act 1970 was passed which allowed only process patents for new molecules and chemical entities (NCEs). This law opened gates for reverse engineering of medicines thus brought down price of medicines in India to affordable level. However the post TRIPS (i.e. post 1995) era has seen the paradigm shift from generic product development to innovative R&D and basic R&D. The legal issues mainly focus on the effective enforcement of patent laws in India. If we look at the history, the Indian pharma companies have flourished due to weaker Indian patent law. However as a legal binding, Indian government being a signatory to TRIPs implemented product patent system in India. The developed nations backed by MNCs are putting pressure of Indian Government to implement strict patents laws in view of TRIPs agreement. The ethical issues highlight the access and affordability of essential medicines to Indian citizens. It is well known fact that the strict patents reduce the availability and affordability of new essential drugs in developing countries, and thereby have a negative impact on the health of poor patients. There are few legal tools available in the TRIPs such as compulsory licensing which needs to be fully exploited by Indian government.

Biography

B. S. Kuchekar has completed his Ph.D. degree in Pharmaceutical Chemistry in 2002. He has 33 years experience in academics. He has published 135 research papers and 29 reviews. 4 books and 2 patents are to his credit. He has guided 45 postgraduate and 8 Ph.D. scholars. He did LL.B. from New Law College Pune, India and P. G. Diploma in Patents law from NALSAR University, Hyderabad. Currently he is working as a Principal and Professor at Maharashtra Institute of Pharmacy, MIT campus, Pune, India.

bskuchekar@rediffmail.com

New drug application under section 505(b) (2): Preferred USFDA regulatory approval pathway

Balaram Gajra
Charotar University of Science and Technology, India

United States Food and Drug Administration (USFDA) has three sections of New Drug Application (NDA) approval pathway: Section 505(b) (1), 505(b) (2) and 505(j). 505(j) is known as Abbreviated New Drug Application (ANDA). According to section 505(b) (1) or full NDA, the application must contain full reports of investigations of safety and effectiveness. 505(j) or ANDA is for a proposed drug that is identical to a reference listed drug and must demonstrates its bioequivalence and the product is called as generic drug product. The 505(b) (2) is intermediate of full NDA and the ANDA, it proposes a limited change to a previously approved product and demonstrates the required safety and efficacy of the change. The changes to approved drugs which would be appropriate to submit as 505(b) (2) applications are changes in dosage form, strength, formulation, dosing regimen or route of administration; a new combination product, including substitution of an active ingredient; modified active ingredient (i.e. salt, chelate, ester, complex, etc.); new indications for previously approved drugs; over-the-counter switch of an approved prescription drug. In fiscal year 2006, approximately 20% of new drugs were approved through the 505(b) (2) process. In 2007, the number was about 43%. In 2008, more than half of the new drugs approved in the United States were based on the 505(b) (2) process. This figure has been increased to 65 % in 2009 and it is expected that by the end of 2012 it will raise to 90 %. The reasons behind increase in the number of the applications under 505(b) (2) are its advantages over the 505(b) (1) such as: eliminates the duplicative costly and time consuming clinical studies, applicant may qualify for 3-5 years of market exclusivity, less cost, less risk, less time consuming than the full NDA.

Biography

Balaram Gajra has completed Masters from Banaras Hindu University, Varanasi, India and Ph.D from Faculty of Pharmaceutical Sciences, Kachchh Universuty, Bhuj, India. He is Associate Professor at Ramanabhai Patel College of Pharmacy, Charotar University of Science and Technology, India. He has published more than 12 papers in reputed journals and presented more than 30 papers in national and international conferences. Currently he is guiding 5 Masters projects and 2 doctorate projects.

balaramgajra.ph@ecchanga.ac.in