Journal of
Cancer Science & Therapy

Bisen, J Cancer Sci Ther 2013, 5.6
DOI: 10.4172/1948-5956.1000e123

Editorial Open Access

Rewarding Incremental Innovation in Cancer Research

Prakash S Bisen*

Center for Innovative Technology, Vikrant Institute of Technology and Management, Gwalior 474005, India

The landmark decision to rejection of patent to anti-cancer drug 'Glivec' by Indian Supreme Court has catalysed range of debates around importance of innovation in research and development. The patent plea by Novartis for beta crystalline for of imanitib (i.e. glivec) was considered as an attempt to extend period of market exclusivity by filing patent for minor modification of molecule for which US patent was already been granted on 1996. Novartis has firmly stated court's ruling as a setback to patent protection for its years of research invested in development of more stable and bioavailable form of imanitib, and offended by this decision they have issued host of statements about not investing in drug discovery R&D in India, and have also raised doubt about launching new life saving drugs in markets with poor patent protection environment like India.

On the surface concerns expressed by Novartis may look quite convincing; however after reviewing history of imanitib and its subsequent refinement into glivec, one cannot avoid thinking about it as a typical case of *patent evergreening* [1-3]. The cause of disagreement in this patent war is section 3(d) of Indian Patent Act, which limits scope of incremental innovation by recognizing only those incremental inventive steps, which are associated with significant increase in efficacy of drug; this section was added with an intention to curb *evergreening*. The importance of controlling patent *evergreening* cannot be denied, especially for developing and underdeveloped nations, which cannot afford to buy patented drugs at premium price to meet their health care requirements and are heavily dependent on generic version of the drug, as is evident from the impact of availability of low cost generic version of anti-retroviral drugs. At the same time, we cannot deny importance of incremental innovation in making effective and safer drug.

The existing content of section 3(d) of Indian Patent Act could dissuade domestic as well as international innovators involved in drug research and development. There is a pressing need to redefine section 3(d) of Indian Patent Act to differentiate between genuine incremental innovations against *evergreening*. This can be done by removing any ambiguity in section 3(d) with regards to existing terms like efficacy/ significantly etc. as well as increasing scope by adding important attributes like safety, bioavailability etc. which will reward genuine incremental innovation. Such amendments will help India in long term, as our research activities are more tuned for incremental innovations, which are more economically viable than inventing blockbuster drugs, which depend upon costly, and long-term investments. Any such amendment in Indian Patent Act would be possible only after careful consideration of its impact on domestic pharmaceutical industry, which at present is dominated by generic players. Moreover, such amendment should be backed by proper legislation. However, such change in policy may take years for implementation. This delay would place patients in precarious condition and they would be devoid of treatment by improved/latest pharmaceutical interventions.

The epidemiological profile in developing and underdeveloped countries is witnessing transition from communicable to non-communicable diseases, which essentially means there would be increase in diseases like cancer, hypertension, diabetes etc., which were previously predominant in developed countries. According to latest survey, about 0.56 million people in India died from cancer in 2010 [4]. Oral and lung cancer are two most common fatal cancers in Indian men. Cervical, stomach and breast cancers are most common type of fatal cancers among Indian women, accounting for over 41% of cancer deaths among women in India.

The dominance of big pharmaceutical companies in anti-cancer drug market should be matter of utmost concern for India, especially after current ruling of patent plea, which may be fundamentally correct, has unfortunately raised apprehensions about innovation ecosystem in India. With such uncertainties ahead of us, only best possible solution could be to reduce dependency on big pharmaceuticals by promoting research ecosystem dedicated for drug discovery in environment, which is conducive for innovation. It would not be wise to blindly follow research blueprint from big pharmaceuticals in developed and underdeveloped nations, as it would require large investment, which may be not economically feasible. On reviewing the source of drugs available for cancer treatment, it is inevitable to miss fact that majority of anticancer drugs are sourced either directly for natural bioactive compounds or after structural optimization of natural compound. We will be well placed to meet treatment requirements of cancer patient in our country, if we design our research activities focused around unlimited resource offered by Mother Nature. Anti-cancer activity of compounds isolated from natural resources has been proven in various studies [5-13]. India has strong foundation in alternative medicine systems like Ayurveda, which is now gradually getting acceptance as treatment option for cancer [14,15]. Understanding of molecular events and pathways associated with cancer development and growth [16] is of prime importance for development of safe and effective anti-cancer drug. Compounds extracted from natural sources often have low bioavailability, which makes it difficult to produce desired therapeutic effect in normal dosage. Various compound optimization techniques and/or targeted delivery system can be used to circumvent challenges posed by low bioavailability of natural compound. Existing Indian Patent Act may not protect such optimizations, which could act as a roadblock to research endeavour in the field of cancer therapy.

References

1. Holman CM (2006) Biotechnology's Prescription for Patent Reform. John Marshall Journal of Intellectual Property Law 5: 318.

2. Mueller JM, Chisum DS (2008) Enabling Patent Law's Inherent Anticipation Doctrine. Houston Law Review 45: 1101.

***Corresponding author:** Prakash S Bisen, Center for Innovative Technology, Vikrant Institute of Technology and Management, Gwalior 474005, India, E-mail: psbisen@gmail.com

Received June 16, 2013; **Accepted** June 18, 2013; **Published** June 20, 2013

Citation: Bisen PS (2013) Rewarding Incremental Innovation in Cancer Research. J Cancer Sci Ther 5: e123. doi:10.4172/1948-5956.1000e123

3. Eisenberg RS (2007) The Role of the FDA in Innovation Policy. Michigan Telecommunications and Technology Law Review 13: 345.
4. Dikshit R, Gupta PC, Ramasundarahettige C, Gajalakshmi V, Aleksandrowicz L, et al. (2012) Cancer mortality in India: a nationally representative survey. Lancet 379: 1807-1816.
5. Cerella C, Radogna F, Dicato M, Diederich M (2013) Natural compounds as regulators of the cancer cell metabolism. Int J Cell Biol 2013: 639401.
6. Monro JA (2003) Treatment of cancer with mushroom products. Arch Environ Health 58: 533-537.
7. Borchers AT, Krishnamurthy A, Keen CL, Meyers FJ, Gershwin ME (2008) The immunobiology of mushrooms. Exp Biol Med (Maywood) 233: 259-276.
8. Khan Z, Bhadouria P, Bisen PS (2005) Nutritional and therapeutic potential of Spirulina. Curr Pharm Biotechnol 6: 373-379.
9. Basha OM, Hafez RA, El-Ayouty YM, Mahrous KF, Bareedy MH, et al. (2008) C-Phycocyanin inhibits cell proliferation and may induce apoptosis in human HepG2 cells. Egypt J Immunol 15: 161-167.
10. Hong J, Luesch H (2012) Largazole: from discovery to broad-spectrum therapy. Nat Prod Rep 29: 449-456.
11. Bisen PS, Bundela SS, Sharma A (2012) Ellagic Acid - Chemopreventive Role in Oral Cancer. J Cancer Sci Ther 4: 023-030.
12. Farnsworth NR, Akerele O, Bingel AS, Soejarto DD, Guo Z (1985) Medicinal plants in therapy. Bull World Health Organ 63: 965-981.
13. Amin AR, Kucuk O, Khuri FR, Shin DM (2009) Perspectives for cancer prevention with natural compounds. J Clin Oncol 27: 2712-2725.
14. Sumantran VN, Tillu G (2012) Cancer, inflammation, and insights from ayurveda. Evid Based Complement Alternat Med 2012: 306346.
15. Jain S, Gill V, Vasudeva N, Singla N (2009) Ayurvedic medicines in treatment of cancer. Zhong Xi Yi Jie He Xue Bao 7: 1096-1099.
16. Bisen PS, Khan Z, Bundela S (2013) Biology of Oral Cancer - Key Apoptotic Regulators. CRC Press: 292.