Don’t abuse patents: scientists

The public sector has a key role in drug R&D. Patenting minor changes to extend monopoly prices spells misuse

Date: 5 September 2011

Source: The Livemint

In the recent debates on patents, pharmaceutical prices and access to essential medicines, the critical role of scientists and resources of the public sector and academic institutions involved in medical research have often been overlooked. As one of the scientists behind the development of the medicine ‘imatinib’ (marketed as Glivec by Novartis), which has allowed the effective control of a devastating form of cancer, I have witnessed the vital role that academic researchers and public institutions play in bringing new medicines to the market.

Many scientists, if not most of those I have collaborated with in these settings, are engaged in research primarily motivated by the pursuit of knowledge as a means to help patients. For many of these scientists it is, therefore, of great concern that the results of their efforts can’t reach patients and save lives because of pricing strategies and patent policies such as “patent evergreening” (minor changes to existing molecules designed to extend patent monopolies) used by partners further down the drug development process.

The price at which Glivec has been offered for sale by Novartis is cause for considerable discomfort
Chronic Myeloid Leukaemia (CML) is a disorder of blood cells that transforms through an “accelerated phase” to an invariably fatal leukaemia. Imatinib has radically improved the success of treatment for this disorder and patients treated with the medication can retain a high quality of life. The development of this drug is a journey in scientific discovery that highlights the collaborative and open process of innovation, where both the private and public sectors play an indispensable role. The marketing approval of imatinib was the result of research conducted over decades, marked by international collaboration of scientists from different academic institutions and the private sector.

The basic research that led to the identification of enzyme inhibitors for CML dates back to 1960 with the identification of the Philadelphia chromosome in patients with CML by researchers at the University of Pennsylvania, Peter Nowell and David Hungerford. In 1973, Janet Rowley at the University of Chicago determined that the abnormal chromosome was due to a translocation of genetic material. In the 1980s, several labs, including my own, played an important role in showing how the Philadelphia chromosome produced a cancer

causing protein (Bcr-Abl). This research also clearly suggested that the selective blockade of the Bcr-Abl enzyme could provide a means to control and prevent the progression of CML.

In the late 1980s, I began collaborating with industry scientists at Ciba-Geigy (now Novartis Pharmaceuticals) who were developing inhibitors for the class of enzymes to which Bcr-Abl belongs. Both the scientific community and the pharma industry were highly sceptical of the utility and selectivity of these enzyme inhibitors, and interest was limited. Despite this, I suggested that the CML enzyme (Bcr-Abl) would be an ideal target for therapy.

In 1993, I moved to Oregon Health Sciences University in Portland and had a single goal of finding a company that had the best inhibitor for Bcr-Abl and to bring it into clinical trials. My work in Oregon on a therapy for CML was primarily funded by public sources, particularly the National Cancer Institute. My persistence with scientists at Ciba-Geigy (now Novartis) helped to keep the development of imatinib on their agenda despite uncertainty from product managers. As imatinib progressed through early and late clinical trials and demonstrated outstanding results, scientific and media interest in our discovery increased. The approval of imatinib by the FDA in May 2001 for use in CML was the culmination of a 10-year project for me, something I had dreamed of since medical school.

However, the price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort. Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that make the discovery of these medicines possible.

Public institutions around the world have continuously played a critical role in the research that leads to vital new medicines reaching the market. Without access medical research becomes a luxury good. Most of my colleagues would be very uncomfortable if we felt that this would be the result of our decades ofeffort.

Brian Druker, chair of Leukemia Research and professor of medicine at the Oregon Health and Science University Cancer Institute, is recognized as the key researcher behind the discovery of STI571 or imatinib (marketed as Glivec by Novartis). Comment at theirview@livemint.com

Keywords: Patent / Essential Medicines / Abuse