From “Glivec®” to “Prevnar 13®”: How strong is the Indian drug patenting system?

Sir,

India’s entry into “pharmaceutical patenting” system was well reinforced by the amendments in the Patents Act (2005) with the inclusion of Section 3 (d). Section (d) imposes that the mere discovery of a new form of a known substance (such as the salts, esters, isomers, and others) are not patentable unless they reveal a significant improvement in therapeutic efficacy. The essence of Section 3 (d) was exemplified by the 2013 verdict of the Apex Court in India against granting patent to Novartis’ Glivec®. Glivec® is a β-crystalline form of previously known imatinib used in the management of chronic myeloid leukemia. The rejection of a patent to Glivec® led to the usage of cheaper generic drugs the cost of which was 92% lesser. From there on “The Novartis standard” was considered as the gold standard in granting pharmaceutical patents, especially to incremental innovation (“secondary patents”).

The other notable examples of utilization of Section 3 (d) for rejecting or revoking pharma patents are Roche for Tarceva® (erlotinib hydrochloride), Abraxis BioScience for Abraxane® (paclitaxel protein-bound), Gilead Sciences for Sovaldi® (sofosbuvir) and Boehringer Ingelheim for Spiriva® (tiotropium bromide monohydrate).

Natco, a Hyderabad-based generic pharma company, sought for a voluntary license from the patent-holder Bayer for sorafenib (Nexavar®); Nexavar® is indicated for unresectable hepatic or advanced renal cell cancer. However, Bayer denied it on the grounds of huge R and D cost. However, the IPO provided “compulsory license” to Natco leading to a drastic reduction in the money spent per month, i.e., from lakhs of rupees to a few thousands. “Compulsory license” is offered to an interested third party at any time after the expiration of 3 years from the date of the grant of a patent under the following grounds, namely, the reasonable requirement of the public is not satisfied, the nonavailability of drug at a reasonably affordable price or the absence of working of the patented invention (drug) in India. Nevertheless, the “compulsory license” offered to Natco has been the first and the last successful incident with regard to compulsory licensing practice in India till now. The subsequent attempts by Lee Pharma for AstraZeneca’s saxagliptin and BDR Pharma for Bristol-Myers Squibb’s dasatinib failed even to get an interim injunction as both the cases were not considered a prima facie case for the grant of compulsory licenses. Therefore, it is obvious that India is not totally prejudiced towards the generic manufacturers and the rights of the originators are equally protected based on the pros and cons of the individual case.

On the other hand, in spite of huge uproar from various sections, the IPO granted patent for the 13-valent pneumococcal conjugate vaccine (Prevnar®) to Pfizer last year. This explains the fact that India supports true innovation.

India is rightly considered as “the pharmacy of the developing world”- as it contributes to more than 2/3rd of drugs distributed to third-world countries for HIV, tuberculosis and malaria. Hence, the patenting system in India is of paramount significance not only to the people of India but also for the world community at large.

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REFERENCES
1. The Patents Act; 2017. Available from: http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf. [Last accessed on 2018 Jul 25].
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2. Gabble R, Kohler JC. To patent or not to patent? The case of Novartis' cancer drug Gleevec in India. Global Health 2014;10:3.
3. Arora S, Chaturvedi R. Section 3(d): Implications and key concerns for pharmaceutical sector. J Intellect Prop Rights 2016;21:16-26.
4. Chaudhry R. Compulsory licensing of patents in India. Pharm Pat Anal 2016;5:401-6.
5. India Grants Pfizer Patent on Pneumonia Vaccine in Blow to aid Group | Reuters; 2017. Available from: https://www.reuters.com/article/us-pfizer-india-vaccine/india-grants-pfizer-patent-on-pneumonia-vaccine-in-blow-to-aid-group-idUSKCN1B218S. [Last accessed on 2018 Jul 25].

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