WIPR
WORLD INTELLECTUAL PROPERTY REVIEW

Protection of medical devices in India

18-12-2015

Vivek Kashyap and Neha Mittal

The medical device industry in India is estimated to be worth around $3 billion and is expected to grow substantially, with a wide variety of life-saving and non-life saving medical devices including domestic as well as imported products. Imported products account for about 75% of total sales.

Patents are the inseparable attendant of innovation and innovative products. Numerous patent applications on medical devices are filed every year, reflecting the scale of innovation in this field and value of the healthcare sector. The Indian Patents Act, 1970 and the Patents Rule, 2003 govern the protection of patents in India. The act provides protection for both products and processes.

Medical devices, as instruments or apparatus, are protectable under the act. However, innovations arising in the medical device field may experience challenges from some exclusions such as sections 3(d), 3(f) and 3(i) of the act, particularly the provision of section 3(d), which is unique to India. This imposes an obligatory requirement on the applicant to make an assessment of the aforesaid sections at an early stage, probably at the drafting stage, to ensure a secure protection of medical devices.

The exceptions under the act can make the prosecution of medical devices challenging. Institutions, whether domestic or international, that are making innovations in the field and filing patent applications in India need to take note of these exclusions to ensure smoother prosecution and grant of patents.

In addition to pharmaceutical products and processes, which are often challenged under section 3(d), innovations relating to medical devices can also be challenged through section 3(d).

Section 3(f) of the act requires a medical device innovation to demonstrate that the said device is not a mere arrangement or re-arrangement of known devices. This section creates

patentability issues for medical devices with incremental improvements. For incremental innovations, it is essential for the innovators to demonstrate that such incremental improvement shows a unique combination of components and results in a better medical device in terms of expeditious process in a more economical manner. More specifically, if such incremental inventions can be shown to have more affordable and economic value then they are likely to fall outside the scope of the said section.

"The protection of innovations relating to medical devices in India is allowed, but medical device patent applications can face challenges from the exclusion to patentability."

Section 3(i) of the act creates impediments in respect of device innovations, particularly for those device innovations which function/work directly on humans or animals or parts of them. The complexity of this section needs to be understood in respect of its application, where if a medical process is used on humans or animal subjects, rendering the said subjects free of disease or any ailment, then such process will be excluded from patentability. For example, a method for operating a pacemaker so that its output to the heart was adjusted was denied from being patented as this amounted to a method of treatment. Other non-limiting examples include surgical procedure devices, a device for purifying blood, and a device for monitoring drug delivery. Hence, innovators should ensure that their patent application is drafted to avoid the exclusions relating to medical methods. More specifically any device performing an *in vivo* function on human or animal subjects will be excluded from patentability under the said section. Any device performing a treatment process can face challenges under this section.

The protection of innovations relating to medical devices in India is allowed, but medical device patent applications can face challenges from the exclusion to patentability as discussed in the above sections. Usually applicants draft their applications on the basis of the important markets, including the US and Europe, but applicants intending to protect their medical device innovations in India are recommended to seek professional advice from local attorneys to ensure the best possible means to avoid being hit by patentability exclusion sections during prosecution.

Applicants should consider obtaining professional help at the time of drafting their patent application as this will enable the applicant to append necessary descriptive features, and if needed specific examples that will address the issues arising out of the patentability exclusions at the time of filing the application. This will enable the applicants to have a better understanding of the territorial exclusions pertaining to India and will also put their patent applications in a safe harbour during the prosecution stage.

Vivek Kashyap is a senior associate at Lex Orbis. He can be contacted at: vivek@lexorbis.com

Neha Mittal is a principal associate at Lex Orbis. She can be contacted at: neha@lexorbis.com