Patent issues for the Indian life sciences industry

As the Indian patent regime is continually evolving, applicants seeking to protect their inventions in India must pay careful attention to the legislation and Patent Office guidelines

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The life sciences industry has the potential to offer many innovative products for the betterment of society, especially in relation to healthcare. This has led many companies – both start-ups and large organisations – to invest in the sector and implement measures to protect their innovative products and processes. Most innovations in the global life sciences industry relate directly to human health and therefore come under close scrutiny from both governmental and non-governmental bodies. This poses a number of challenges when protecting such innovations through patents.

This article discusses some of the issues faced by patent applicants in the life sciences sector in India (especially for inventions related to drugs, medicines and vaccines), examines the relevant provisions of the Patents Act 1970 and describes the possible actions that applicants may consider to protect their innovations in the country.

The patenting trend

Indian patent policies and their effect on investment by the life sciences industry in the country have been the subject of debate for some time. Nevertheless, the number of patent applications filed in India has risen steadily over the past five years, as evidenced in the Annual Report 2012-2013 recently issued by the Indian Patent Office. This increase in patent filings has also been observed in the chemical, biotechnology, drug and food technology sectors during this period, when compared to previous years. This trend has also been observed in relation to the granting of patents in these sectors, except for biotechnology.

New form of known substance

The most discussed provision of the Patents Act is Section 3(d), which prohibits patenting of "a new form of a known substance which does not result in the enhancement of the known efficacy of that substance". Although the term 'efficacy' is not defined in the act, in 2013 the Supreme Court provided guidance for assessing 'enhanced efficacy' in a case involving Novartis's Gleevec drug (*Novartis v Union of India* (2013), Case 2706-2716). The court noted that the term 'efficacy' will differ from case to case, depending on the product under consideration. However, it indicated that efficacy should relate to the desired or intended result to be produced by the product under consideration. The court clarified that the test of efficacy will also depend on the function, utility or purpose of such product. Accordingly, for a medicine that claims to cure a disease, the test of efficacy will be its therapeutic efficacy.

Some of the objections raised by Section 3(d) may be overcome either by establishing that the claimed product is not a new form of a known substance or by providing evidence that the claimed product has better or enhanced efficacy than the known forms. While assessment of whether a claimed product is a new form or derivative is subjective (ie, depending on how an examiner looks at it), a claim will always be supported if evidence of enhanced efficacy is provided, regardless of

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whether the claimed product is derivative or a completely new compound or product. Therefore, when writing patent applications, instead of considering Section 3(d) separately, applicants should consider it in association with the requirement to establish an inventive step and the support or enablement requirement. These two requirements (ie, inventive step and support or enablement of the patent application) are universally applicable, although there is a certain degree of variation in the applicable thresholds for different countries.

If a product claims a particular function, its utility or function must also be shown in the application, by way of examples. If a product claims to treat disease X, most national patent laws will require some experimental data to show that the claimed product indeed has the potential to treat disease X. Applicants that intend to obtain patent protection in India for their products must consider performing tests that compare the effects of the claimed product with those of the closest available prior art products. This will generally help in establishing the patentability of the invention, including inventive step, and overcoming any objections under Section 3(d). When writing patent applications, if applicants incorporate such experimental data, their chances of obtaining a patent in India will greatly increase. Furthermore, the Patent Office grants patents wherever the applicant has presented comparative examples to demonstrate an increase in the desired efficacy as compared to the closest known form.

Permission from National Biodiversity Authority

Another typical requirement under the Patents Act relates to use of biological resources, or information based on such resources, obtained from India in the invention. The Patent Office has recently started taking into account the requirements of the Biological Diversity Act 2002 in relation to patent applications. Section 6 of the act requires applicants whose inventions or applications are based on research or information relating to 'biological resources' – defined in Section 2(c) of the act as "plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value but does not include human genetic material" – originating from India to obtain permission from the National Biodiversity Authority (NBA) when applying for IP rights. This provision will generally apply to Indian applicants and to those multinationals that have their R&D centres in India. Such permission must be obtained from the NBA before a patent can be granted. This provision allows the benefits arising out of the commercialisation of such inventions to be shared with local communities.

Breach of these provisions can result in penalties, including imprisonment for up to five years or a fine of up to Rs1 million (approximately $16,000). In cases where the damage caused exceeds Rs1 million, such fine may be commensurate to the damage caused. Applicants whose patent applications use biological resources

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from India, or are based on research and information on biological resources obtained from India, need not withhold their applications until the NBA's approval has been obtained. Such permission can be sought even after the application has been filed in India, but must be obtained before the patent is granted. In this regard, the Patent Office also appears to be accommodating for those applications that are already under examination, although it has often recommended and instructed applicants to obtain approval from the NBA before the patent can be granted. Foreign applicants whose patent applications do not use biological resources originating from India need not apply for permission from the NBA for their IP rights.

Traditional knowledge

The Patents Act prohibits the patenting of inventions that are in effect traditional knowledge. In this regard, there is no restriction on the particular community or geographical area to which such knowledge pertains; traditional knowledge from anywhere in the world will be considered. Even the aggregation or duplication of known properties of traditionally known components cannot be patented.

To assist applicants in checking whether their invention will be considered traditional knowledge, a traditional knowledge digital library has been established by the Council of Scientific and Industrial Research in collaboration with the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. The Patent Office has cited documents from this library when assessing the inventive step for inventions based on plants or alternative medicines. Hence, applicants may choose to conduct a search of the library before starting or progressing with an invention based on plants or herbs.

General patenting issues

Although some provisions related to patenting (eg, claim language and definitive scope of claim) are applicable worldwide, in India these are generally governed by the typical practice that has developed over time in the patent system.

Claim language

One of the most frequent objections in India for inventions in the life sciences sector, especially in biotechnology, is non-definitiveness of claims. In biotechnology, the product (eg, an antibody) is often described by its function, rather than by its composition or construction. Such claims are usually considered vague and indefinite by the Patent Office. Applicants may therefore need to highlight those aspects of the application that demonstrate the definitiveness of their claims. Explaining the claim and showing how it has a defined scope will often help in such a claim being accepted.

In addition, product-by-process claims are usual when the product itself cannot be defined by its constructional features. Product-by-process claims are allowed in India, provided that the product is novel in itself and it can be shown that it is difficult or unfeasible to define the product clearly by its constructional features.

Method of treatment

Some patent offices (eg, the US Patent and Trademark Office) allow claims related to method of treatment, but others (eg, the European Patent Office and the Indian Patent Office) do not. The Indian Patent Office does not allow even second medical use claims, which are generally allowed by the European Patent Office. Section 3(i) of the Indian Patents Act excludes "any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for the similar treatment of animals to render them free of disease or to increase their economic value or that of their products". This exclusion exists more as a policy that skilled professionals practising in these areas who use these methods as a part of their duties should not be restricted as a result of patent protection arising from these methods or treatments.

The act does not define the meaning of the terms 'medicinal', 'surgical', 'curative', 'prophylactic', 'diagnostic' or 'therapeutic' treatments. However, the Indian Patent Office has tried to explain these terms by way of examples, controller decisions and precedents from other countries in its manual of practice and procedure. Nevertheless, certain exceptions are possible if the claims relate to surgical, therapeutic or diagnostic instruments or apparatus. In addition, *in vitro* diagnostic methods are patentable if they are performed outside the body (ie, on extracted tissue or fluids from a human or animal body).

Unity of invention

In the life sciences sector, especially in biotechnology, it is usual practice to include multiple independent claims directed towards multiple related inventions. The Indian Patent Office is usually rigorous in its assessment of the plurality of distinct inventions and often tends to discourage multiple inventions submitted in a single application. However, the Patents Act does allow multiple inventions if it can be established that the distinct inventions are linked so as to form a single inventive concept. If a single inventive concept cannot be established, the applicant can seek protection for the non-accepted inventions in one or more divisional applications. However, the applicant must take care with regard to the timing of such applications: any divisional application must be filed before grant of the first parent application. Although there has been some inconsistency regarding the deadline for filing divisional applications, the prevailing practice is that a divisional application filed before grant of the first parent application will be safe.

In addition, a divisional application must contain claims that are distinct from those of the parent application. Therefore, filing a divisional application that refiles the claims of the parent application solely in order to keep an application pending is unacceptable in India. Such divisional applications have been held invalid where they did not contain claims distinct from the parent application or patent. The most suitable time for strategising the filing of divisional applications is during the prosecution or examination stage of the parent application, based on the objections raised in relation to a lack of unity of invention.

Conclusion

The Patents Act 1970 has undergone numerous changes since its introduction. Along with the changes in law, the practices of the Indian Patent Office are constantly developing and it is well on the way to achieving digitisation, transparency and consistency in practice. The Patent Office has already issued guidelines for the examination of inventions related to biotechnology and traditional knowledge, and the draft guidelines for the examination of inventions related to pharmaceuticals are open for public comment. Applicants that hope to protect their inventions in India — a sought-after market for products from the life sciences sector — are therefore advised to consider the Patents Act when writing their applications. Most information related to patent applications, controllers' decisions and examination guidelines is made available online by the Patent Office. Such developments pave the way for the development of consistent patent practice, which should help applicants to protect their inventions effectively. ■

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