Protecting inventions in the life sciences sector

Although the life sciences industry offers huge potential for profit, rights holders must first negotiate a sensitive and complex legal framework

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With a total population of around 1.27 billion, India is the second-most populous country in the world after China. Given its size, India is naturally a major market for all industries, including life sciences.

India is among the top 20 pharmaceutical exporting countries; in 2010-2011 the annual turnover of the Indian pharmaceutical industry was estimated to be around $18.54 billion.

The Indian biotech industry is also poised for robust growth and international participation in the future. According to the 10th annual Indian biotech industry survey conducted by Biospectrum - Association of Biotechnology-Led Enterprises, the Indian biotech industry passed the $4 billion mark in 2011-2012, growing by 15% compared to the previous year.

Trends at the Patent Office

Patent applications at the Indian Patent Office increased by 15% in 2011-2012 compared to 2010-2011.

During 2010-2011, 39,400 patent applications were filed. The Patent Office granted 7,509 patents; 5,186 were abandoned, 54 were refused after examination and 102 were withdrawn by the applicants.

Given the huge proportion of patents filed for life sciences inventions, it is important to understand the issues and to devise strategies for achieving success at the Patent Office.

Major objections to life sciences inventions

The legal protection framework for life sciences-related inventions is sensitive and

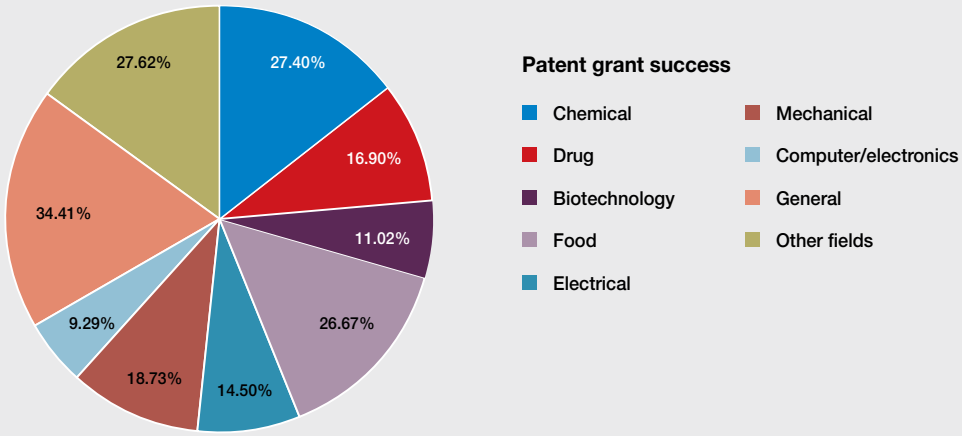

Figure 1. **Patents granted in various fields of technology in 2010-2011**

> **“An invention which is, in effect, traditional knowledge or an aggregation or duplication of known properties of traditionally known components is also not patentable subject matter under the act”**

complex due to the technical and ethical issues involved. Apart from the basic parameters of novelty, inventive step and industrial applicability, which are considered while granting a patent in India, certain other factors must also be taken into account – since objections to these factors are more commonly raised for life sciences-related inventions. The objections which are generally raised in relation to life sciences inventions are as follows.

Section 3(d)

The discovery of a new form of a known substance which does not improve efficacy, or of a new use of a known substance, is not considered to be an invention under the Patent Act. Therefore, if a drug is already known for treating one disease, its use to treat another disease cannot be patented, however unexpected the new use may be.

The significance of Section 3(d) is such that it has affected business decisions to the point of investments in India being frozen and diverted to more patent-friendly territories by innovative life sciences companies. The Supreme Court decision rejecting a patent application filed by Swiss pharmaceutical Novartis for Glivec (beta crystalline Imatinib mesylate) is an example of the deadly effect of Section 3(d). The Supreme Court rejected the patent application on the grounds that Glivec was only a new form of a known substance, Imatinib mesylate, and there had been no enhancement in efficacy. Thus, it was not patentable under Section 3(d). Although Novartis had provided data in the specification which exhibited a 30% increase in bioavailability as compared to Imatinib, the court clarified that increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. However, the decision also stated that whether an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data which leads to an inference that increased bioavailability – which translates into an enhancement in efficacy – might be useful to overcome objections to Section 3(d).

Protecting a life sciences invention also requires success at the Patent Office at the prosecution stage. However, the most common and frequent objections raised by the Patent Office to life sciences inventions involve Section 3(d).

The patent controller's December 2012 decision on Application 106/DELNP/2008 regarding polymorphic forms appeared to provide guidance on overcoming Section 3(d) objections at the Patent Office. The controller felt that the enhancement in efficacy lay in the fact that the polymorph for which the patent application was filed showed an *in vivo* absorption level which was about 100 times lower than the original form. This resulted in a reduction of toxicity by 100 times due to reduced absorption. The controller held that a hundredfold reduction in toxicity while maintaining efficacy was appropriate for overcoming a Section 3(d) objection. Thus, the Patent Office may accept reduced toxicity with the same efficacy as a measure of enhanced efficacy.

Section 3(e)

A mere mixture resulting only in the aggregation of properties or a method of making such mixture is also not considered to be patentable, as an aggregation in the properties of such mixture is expected.

For the purposes of the act, a mixture resulting in synergistic properties is not considered to be a mere mixture. A soap, detergent, lubricant and polymer composition may be considered to be patentable if it exhibits a synergistic property. The existence of a combination invention requires that either the relationship between the features or groups of features be one of functional reciprocity, or

the features or groups of features demonstrate a combinative effect beyond the sum of their individual effects.

Section 3(i)

A method of treatment for human beings, or a process for a similar treatment for animals to render them free of disease or to increase the economic value of the animals or their products, is not an invention under the act. This prohibition covers any process for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment.

Further, methods of diagnosing or preventing a disease, administering a drug, surgically removing cancerous tissue or treating or curing a disease are non-patentable.

In January 2012 the Patent Office rejected Application IN/PCT/2001/1008/KOL, entitled "Method for programmed controlled ovarian stimulation protocol", wherein the main claim related to therapeutic management of infertility. The Patent Office objected to the claims on the grounds of Section 3(i) – method of treatment. In response, the claims were converted to a pharmaceutical kit. After revision, the claims were directed to products rather than to the method of treatment. However, the Patent Office believed that the revised claims were inconsistent with the object of the invention. Further, the Patent Office observed that there was no reference to the alleged kit anywhere in the original specification. The Patent Office held that a mere revision of claims or the insertion of a statement at the beginning of the specification did not change the original scope of the invention; hence, the application was rejected under Section 3(i).

In a May 2013 decision the Patent Office rejected Application 3336/CHENP/2006 related to a method to reduce pathogens in biological samples such as blood. The description also mentioned transfusion/reinfusion of the fluid. Therefore, the invention was considered to be a method of treatment, irrespective of its place of operation (ie, *in vitro* or *in vivo*).

On the other hand, the positive aspect related to Section 3(i) is that inventions requiring the skill and knowledge of a surgeon are beyond the purview of the section, and include, for example, cosmetic treatments. Moreover, instruments and apparatus used for surgical, therapeutic or diagnostic purposes are considered to be patentable subject matter, as is the manufacture of prostheses or artificial limbs.

Section 3(j)

Plants and animals, parts thereof and any seeds, varieties or species other than micro-organisms and essentially biological processes do not constitute patentable subject matter under the act.

In May 2013 a patent was granted to Application 3098/DELNP/2006 for an invention entitled "Method for expression of apolipoprotein in plants".

The original claim was rejected since Claim 1 appeared to fall under Section 3(j) because the method involved Step C, which defined the growth of plant cells into mature plants – an essential biological step in the growth of plants. However, Step C was amended to relate to the expression of the apolipoprotein in the plant cell or progeny, and such amendment resulted in the grant of the patent.

Section 3(p)

An invention which is, in effect, traditional knowledge or an aggregation or duplication of known properties of traditionally known components is also not patentable subject matter under the act.

The 'traditional knowledge' referred to in the act is understood to be India's rich traditional knowledge which has been passed down over the generations, either by word of mouth or in ancient classical texts and other literature. As this knowledge already exists, it is not patentable. The pesticidal and insecticidal properties of neem or the antiseptic and healing properties of turmeric could be considered to be traditional knowledge. Application 1576/DEL/2006, which claimed a herbal composition comprising neem, berberis and chakshu for the treatment of skin disorders, was refused by the Patent Office on December 27 2012 on the grounds of traditional knowledge.

The Traditional Knowledge Digital Library (TKDL) project began in 2001. In the past, objections based on traditional knowledge were not considered to be strong objections due to lack of documentation. However, the TKDL gives legitimacy to existing traditional

knowledge and enables the protection of such information against patenting. The TKDL provides information on traditional knowledge that exists across the country, in languages and formats that are understandable by patent examiners at international patent offices.

As of March 2013, 139 patent applications worldwide had been rejected or had claims amended based on objections raised based on traditional knowledge using the TKDL.

Due to the complex ethical and moral issues involved in life sciences-related inventions, in March 2013 the Patent Office issued guidelines for the examination of patent applications related to biotechnology. These guidelines are intended to help Patent Office examiners and controllers to achieve uniformity and consistency. However, in the introduction to the guidelines the Patent Office accepts that they do not constitute rules and, in case of any conflict between the guidelines and the Patents Act 1970 and the Patents Rules 2003, the legislation will prevail over the guidelines.

Compulsory licensing

Over the past decade, compulsory licensing has been adopted by various developing countries. Indonesia granted compulsory licences for various HIV drugs in 2004, 2007 and 2012. Thailand granted a compulsory licence for Kaletra in 2007, and in the same year Brazil granted a compulsory licence for Efavirenz. Ecuador issued compulsory licences in 2010 for Kaletra and for a combination of Abacavir + Lamivudine in 2012. However, in India, compulsory licences have assumed great importance as India is the largest supplier of generic anti-retrovirals to middle and low-income countries.

India's first compulsory licence was granted to Natco by the controller general of patents, designs and trademarks for Bayer's kidney cancer drug Nexavar on March 9 2012. In total, there have been three decisions on this compulsory licence. In the first decision, the Patent Office stated that "mere importation cannot amount to working of a patented invention". Further, that decision held that "worked in the territory of India" means "manufactured to a reasonable extent in India".

The second decision was the Intellectual Property Appellate Board (IPAB) order of September 14 2012 for the stay of the compulsory licence pending appeal. Here, the IPAB felt that "the respondent did not contest the position that 'working' includes importing; only it was qualified that the Act leaned towards local manufacture". The IPAB accepted that for the purpose of deciding the stay petition, the appellant's imports amounted to "working", but at the time of final hearing a deeper examination of the meaning of 'working' would be required.

Finally, on March 2 2013 the IPAB ruled on the appeal of the controller's decision. The IPAB decision stated that it could not be held that 'working' totally excluded import or was synonymous with 'import', and that if there was no manufacturing in India, then there was no working. The IPAB also felt that the word 'worked' had to be interpreted on a case-by-case basis, and while it may be proved in a given case that working can be done only by way of import, that cannot apply to all other cases. Thus, although the IPAB upheld the compulsory licensing order, it was of the opinion that the word 'worked' had a flexible meaning. To that extent, the IPAB differed from the Patent Office.

The IPAB order stated that in some cases 'working' could mean completely local manufacture, but in other cases it could mean only importation. However, it depends on the facts and evidence of each case.

Aligning patent and business strategy

Despite the challenges outlined above, the outlook for the life sciences industry in India is promising. By the end of 2020 the projected value of the Indian pharmaceuticals market is estimated to be around $85 billion. During 2012, the biotechnology sector in India reached an estimated value of $3.8 billion, and this figure is forecast to reach $10.4 billion by 2015. However, exploiting the life sciences industry's huge potential for profits involves a proper understanding of the issues involved in protecting inventions in India. In order to protect and benefit from a life sciences invention in India, it is vital that parties find a balance between their business strategy, the patent strategy guidance of the Supreme Court and Patent Office decisions.

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