

Published by **iam**[®]

Intellectual Asset Management
Yearbook
2016

*Building IP value
in the 21st century*

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law, practice and challenges**

Remfry & Sagar
Debashish Banerjee and Pankaj Musyuni



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Remfry House at the Millennium Plaza
Sector 27, Gurgaon - 122 009
New Delhi National Capital Region, India
Tel : 91-124-280 6100 Fax : 91-124-280 6101 & 257 2123
E-Mail: remfry-sagar@remfry.com
<http://www.remfry.com>

376-B (Old No.202)
Avvai Shanmugam Salai, Gopalapuram
Chennai - 600 086, India
Tel & Fax : 91-44-4263 7392
E-Mail : remfry-sagar@remfry.com
<http://www.remfry.com>

India

Biotechnological inventions in India: law, practice and challenges

By **Debashish Banerjee** and **Pankaj Musyuni**, Remfry & Sagar

Indian patent filing and jurisprudence in the biotech domain have seen neither the volume nor the attention enjoyed by the pharmaceuticals and telecommunications domains. Statistics published by the Indian Patent Office (IPO) for the five-year period from 2008 to 2013 reveal that while overall patent filing figures rose 18.6%, the biotech sector witnessed a decline of 55%, from 1,844 patent applications in 2008-2009 to 832 filings in 2012-2013. The numbers fell even more in terms of granted biotech applications, from 1,157 to just 144.

This negative trend may be attributed to several factors:

- narrow standards of patentability;
- a prohibitive filing fee for sequence listings;
- burdensome requirements (eg, mandatory disclosure of the source and geographical origin of biological material); and
- the hurdle of prior approval from the National Biodiversity Authority (NBA).

This chapter examines the legal framework for protecting biotech patents and the factors hindering optimal growth in this space.

Statutory hurdles to patentability

As well as meeting the patentability requirements of novelty, inventive step and industrial application, a biotech invention must constitute patent-eligible subject matter. Some inventions are excluded from patentability under Section 3 of the Patents Act 1970 – for biotech patents, Sections 3(b), (c), (d), (e), (h), (i), (j) and (p) are relevant.

Section 3(b) stipulates that an invention is ineligible for protection if its use or commercial exploitation is “contrary to public order or morality” or “causes serious prejudice to human, animal or plant life or health or to the environment”. For example, only genetically modified biological materials which cause no prejudice to human, animal or plant life or to the environment are patentable.

Another key provision is Section 3(c). This mandates that the “discovery of any living thing or nonliving substances occurring in nature” does not constitute patent-eligible subject matter. For example, the extraction and isolation of biological materials is generally considered the mere discovery of a naturally occurring substance and is therefore barred under this provision. The recently released IPO Guidelines on the Examination of Biotechnology Applications for Patents expressly state that sequences isolated directly from nature are not patentable. In fact, under existing jurisprudence, only biological materials obtained as a result of substantial human intervention are considered patentable.

Section 3(d) is one of the most controversial provisions of Indian patent law from an innovator’s perspective. This is mainly due to its broad applicability across almost all fields of technology and the extensive leeway afforded to authorities in its interpretation, the pitfalls of which have recently come to the fore in several pharmaceutical battles. For biotech patents, this section is frequently cited in respect of modifications of an existing substance. A limited exception in the sense that it

does not set an absolute bar, Section 3(d) rules out patentability if modification of an existing substance does not yield a “new form of a known substance” which exhibits “enhancement of the known efficacy”. Some parameters for enhanced efficacy for pharmaceuticals have emerged from court decisions; however, in terms of biotech inventions, the nuances of this expression are not yet known.

Another common hurdle is Section 3(e), which excludes from patentability “a substance obtained by mere admixture” and any process for its preparation. Combination vaccines invariably invite proscription under this clause. Under existing practice, a composition comprising known components is considered patentable only if it exhibits synergism. However – akin to ambiguities surrounding enhanced efficacy under Section 3(d) – synergism regarding biotech patent applications lacks a clear statutory definition, leaving the IPO to determine patentability issues on a case-by-case basis.

An applicant’s difficulties do not end here. Under Section 3(h), which stipulates that “a method of agriculture or horticulture” is unpatentable subject matter, the IPO automatically objects to biotech inventions pertaining to the fields of agriculture and horticulture. The recent guidelines have helped to a limited extent by clarifying that Section 3(h) is applicable only to “conventional methods” performed on open fields.

Other frequent objections during the prosecution of biotech inventions stem from Section 3(i), which excludes from patentability “any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products”. Significantly, however, in several instances the IPO has granted patents for *in vitro* diagnostic methods performed on tissues or fluids which had been permanently removed from the body. However, the guidelines brought *in vitro* diagnostic methods under the remit of Section 3(i), so the IPO is unlikely to grant such patents in future. The guidelines do not have the force

of law and are subject to revision based on interpretations by higher judicial authorities. To date, the courts have not yet ruled on whether *in vitro* diagnostic methods can be considered outside the scope of Section 3(i), but it is hoped that the courts will adopt a liberal interpretation when the time comes.

Objections under Section 3(p) also arise quite often. This section categorically excludes from patentability an invention which in effect “is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components”. To clear the qualifying bar set by this provision, claims are examined against searches of traditional knowledge databases, including the Traditional Knowledge Digital Library. Inventions which typically come under the scanner for ineligibility are extracts and alkaloids and active ingredients that are naturally present in plants, combinations of plants with known therapeutic effects, combination products of known active ingredients and discoveries of optimum or workable ranges of traditionally known ingredients through routine experimentation.

One of the biggest impediments to the patentability of biotech inventions is Section 3(j), which is broadly modelled on Article 27.3(b) of the Agreement on Trade-Related Aspects of IP Rights. Section 3(j) excludes from patentability “plants and animals in whole or any part thereof”, “seeds, varieties and species” and “essential biological processes for production or propagation of plants and animals”. Accordingly, methods of crossing and breeding which are essentially biological processes are unpatentable. However, akin to Section 3(b), the bar is lifted in the case of processes involving substantial human intervention. Meanwhile, parallel legislation – the Plant Varieties Protection and Farmers’ Rights Act 2001 – accords *sui generis* protection to transgenic plant varieties.

Decisions

In the context of Section 3(j), the recent decision of the Intellectual Property Appellate Board (IPAB) in *Monsanto Technology LLC v Controller of Patents and Designs* is interesting. Monsanto Technology LLC

“ Under existing jurisprudence, only biological materials obtained as a result of substantial human intervention are considered patentable ”

applied for a patent in respect of a method of producing a transgenic plant that was capable of withstanding harsh environmental conditions. It argued that the production of the transgenic variety involved substantial human intervention in inserting the rDNA molecule into the plant cell and transforming the cell into a climate-resistant plant. However, the IPO was not persuaded and held that the invention claimed related to an essentially biological process of regeneration and selection which was excluded from patentability under Section 3(j) of the patent statute. Further grounds for rejection included lack of inventive step and ineligible subject matter under Section 3(d). On appeal, the IPAB upheld the findings on inventive step and Section 3(d), but disagreed with the IPO on the applicability of Section 3(j). The IPAB unequivocally clarified that the claimed method “includes an act of human intervention on a plant cell and producing in that plant cell some change”, and consequently fell outside the scope of Section 3(j).

A 2002 decision of the Calcutta High Court has played a significant role in the evolution of biotech patent jurisprudence as it stands today. In *Dimminaco AG v Controller of Patents, Designs and Trademarks* Dimminaco AG sought to patent an invention relating to a process for the preparation of an infectious bursitis vaccine, useful for protecting poultry against contagious bursitis infection. The end product contained living organisms in the form of a virus. Looking to the definition of an ‘invention’ under the prevailing patent legislation at the time, the IPO noted that for an invention to be patentable, it must pertain to a “new and useful” manner of manufacture. In its view, the process of preparing a vaccine containing a living virus cannot be considered a manner

of manufacture as “the process has to result either in an article or a substance”. Thus, the IPO rejected Dimminaco’s application.

On appeal, the court applied the ‘vendibility’ test to determine whether the claimed method related to a process of manufacture. Under the vendibility test, the invention must:

- result in the production of a vendible item;
- improve or restore the former condition of a vendible item; or
- preserve and protect a vendible product from deterioration.

In the court’s opinion, “since the process results in a vendible product, it is certainly a substance after going through a process of manufacture”.

In regard to living organisms and patentability, as noted above, some provisions expressly exclude the patentability of sequences isolated directly from nature, but an exception may be carved out for biological materials that are obtained as a result of substantial human intervention. Hailed as a landmark decision, the 2013 US Supreme Court decision in *Association of Molecular Pathology v Myriad Genetics, Inc* saw the court unanimously hold that full-length isolated, naturally occurring DNA molecules/genes or gene fragments are not patent eligible, but are instead “products of nature” that cannot be patented. However, cDNAs – DNA molecules in which the naturally occurring non-coding regions (introns) are absent – were found to be patent eligible. The court reasoned that cDNAs do not occur naturally and are synthesised from RNA in the laboratory, thus validating the patent eligibility of engineered/recombinant DNAs.

To the extent that the IPO guidelines



Debashish Banerjee
Managing associate
debashish.banerjee@remfry.com

Debashish Banerjee is a managing associate. He holds bachelor's degrees in chemistry and law as well as a postgraduate diploma in business management. With more than nine years' experience, he has in-depth knowledge of patent law and extensive experience in both patent prosecution and litigation. He has handled several high-profile litigations before various forums, including the high courts and the Intellectual Property Appellate Board. He has authored several articles on patent law and practice.



Pankaj Musyuni
Senior associate
pankaj.musyuni@remfry.com

Pankaj Musyuni is a senior associate and holds a master's degree in pharmacy and management. A registered pharmacist, he has more than 25 international and national publications, book reviews and chapters to his credit in the fields of pharmaceuticals, agrochemicals and pesticides. He has also delivered talks on drug regulatory affairs and clinical research at various national forums. His practice involves filing, prosecution and opposition of patent applications pertaining to the field of pharmaceuticals.

expressly state that sequences isolated directly from nature are not patentable, they are consistent with the findings in *Myriad*, which require claimed sequences to be structurally different from those found in nature. But the guidelines do not lay down minimum standards for human intervention. In this regard, it will be interesting to see whether the IPO and judicial authorities borrow from *Myriad* at an appropriate occasion to allow applicants to seek protection for cDNA or other recombinant DNA sequences that may be clearly distinguished from naturally occurring DNA.

Some onerous requirements

Apart from the hurdles encountered under Section 3 of the Patents Act and the lack of a significant body of jurisprudence, other burdensome requirements specific to India exist which discourage prospective applicants from filing biotech inventions. For instance, an applicant must pay a filing fee of around

\$13 per page of sequence listing. This places a significant financial burden on patent applicants, especially since biotech inventions are complex and typically may comprise hundreds of pages of sequence listings.

Moreover, Section 10(4)(ii)(D) of the Patents Act mandates the disclosure of the source and geographical origin of biological material whenever these are mentioned in a patent specification, but not sufficiently described in it or made available to the public. A declaration in the patent application form stating that "the invention as disclosed in the specification uses biological material from India and the necessary permission from the competent authority shall be submitted before the grant of patent" is a supplementary requirement. Section 10(4)(ii)(D) was introduced in 2005 to complement the Biological Diversity Act 2002, which aims to protect sovereign rights over genetic resources and specifically requires prior approval from the independent

NBA before applying for a patent for inventions that use biological material from India. However, practice was slow to comply with the 2005 amendment and the NBA approval requirement remained largely theoretical. This has changed recently as the guidelines reaffirmed that NBA approval is a must for the processing of patent applications related to biological material. However, in a perplexing move, the guidelines also prescribe the unreasonable requirement of disclosing source and origin under a separate heading in the specification – irrespective of whether the biological material has been obtained from India or elsewhere.

In itself, obtaining NBA approval poses a serious challenge as this is a cumbersome and lengthy process. Making it a mandatory prerequisite to the grant of a patent will likely contribute to delays in securing a patent successfully. However, the guidelines' second requirement regarding the specification is clearly beyond the statutory mandate – the Patents Act requires disclosure only when biological material is insufficiently described in the specification or is not available to the public – and casts an undue burden on an applicant seeking to patent a biotech invention.

Comment

It would be unfair to pin all of the blame for lacklustre biotech filings on the statutory framework and procedural bottlenecks. Securing IP protection is but one facet of the IP cycle and inhibiting factors are present even when other aspects are considered, such as the creation of IP rights. Biotechnology is a complex business which requires significant investment and India's homegrown biotech industry still has a long way to grow before it catches up with other patent-intensive industries, such as pharmaceuticals.

Further, the various aspects feed off each other. The presence of strong Indian generic companies in the pharmaceutical space has led to conflicting interests between Indian competitors and with multinationals. In turn, this has led to several patent battles before the courts, with the result that pharmaceutical jurisprudence has grown significantly in recent years. The telecommunications sector is following a similar trajectory.

In time, such a pattern is also likely to emerge in respect of biotech patents. Meanwhile, the IPO is trying to clarify procedures and accelerate prosecution. The recent guidelines are a case in point. The IPO is also increasing the number of IPO examiners to address the backlog in examinations. Major expansion of the biotech sector in the near term is expected, promising exciting times ahead for legal practitioners. **iam**



Remfry & Sagar

Remfry & Sagar

Remfry House at the Millennium Plaza
Sector 27

Gurgaon 122009

India

Tel +91 124 280 6100

Fax +91 124 280 6101

Web www.remfry.com