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Coming of age – the Indian product patent regime

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Coming of age – the Indian product patent regime

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In an unprecedented move, Swiss-based pharmaceutical company Novartis AG and its Indian subsidiary have filed two writ petitions at the Chennai High Court. The first writ challenges the constitutionality of the controversial Section 3(d) of the Patents (Amendment) Act 2005 and the provisions of the TRIPs Agreement, to which India is a signatory. The second was filed against an order of the Controller of Patents in a pre-grant opposition. In January 2006, the Controller passed an order refusing grant of patent to the β -crystalline form of the compound imatinib mesylate, also sold in the market as Gleevec, a life-saving drug used in the treatment of chronic myeloid leukaemia.

Both petitions are pending before the Chennai High Court and the outcome is eagerly awaited globally – especially in the life sciences sector in general and the pharmaceutical industry in particular. In India, in addition to the 24,000-strong generic industry and non-governmental organisations, the patent fraternity also has keen interest in the outcome. Since the Patents (Amendment) Act 2005 brought pharmaceutical products within the scope of patentability, Section 3(d) has become a highly contentious point of argument between patent agents and patent examiners.

In light of these writ petitions, the Mashelkar Committee Report on Patent Law Issues, which was submitted to the Indian government on 28th December 2006 and was recently made public, has become highly significant. The report examines the contentious Section 3(d), which is discussed below. It will be interesting to see how the report affects the Novartis writ petitions at the Chennai High Court – and indeed the life sciences industry in the long run.

Background

In order to satisfy its international obligations, including the TRIPs Agreement and the Convention on Biological Diversity (CBD), India has amended the Patent Act 1970 three times. The amendments were staggered to accommodate pressing issues such as exclusive marketing rights, disclosure of the source and origin of biological materials in the patent specification if used in the invention, and streamlining of patent procedures by allowing for the filing of requests for examination. Incidentally, the latter amendment has reduced the period for grant of a patent from seven years to two to three years – and even less where early publication and examination is requested.

The first two amendments to the patent legislation took place in 1999 and 2002. On 1st January 2005, when India amended its patent laws for a third time, the scientific, technical and business communities geared up for intense debate and legal action. One of the more interesting debates and actions playing out in the four patent offices across the country is the patentability of new forms of known substances.

Section 3(d) of the Patents (Amendment) Act 2005

Section 3(d) of the Patents (Amendment) Act 2005 provides as follows:

“Section 3: The following are not inventions within the meaning of this Act...

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers,

mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy..."

Simply stated, to be patentable under the prevailing patent law, new forms of known substances must not only fulfil the three main criteria for patentability – ie, novelty, non-obviousness and industrial applicability – but must also exhibit enhanced efficacy.

Confounding patent applicants, patent agents and patent examiners is the fact that terms such as “efficacy” and “substance” are not defined in the Act. All four patent offices continue to be witness to interesting arguments presented by patent agents on the interpretation of the statutes. Broadly speaking, the debaters are ranged on opposite sides of a single dividing line: what does “enhancement of known efficacy” mean within the context of the Patents (Amendment) Act 2005?

The overwhelming majority argue that the introduction of the term “enhancement of known efficacy” in Section 3(d) has added a new criterion for patentability beyond the TRIPs criteria of novelty, inventive step (also referred to as non-obviousness) and industrial applicability. The Novartis writ petitions appear to be based on this argument.

An alternative argument, which has recently been gaining acceptance among academics, equates “enhancement of known efficacy” with the “surprising effect” requirement, one of the acknowledged standards for inventive step in many patent jurisdictions, including the European Union.

Mashelkar Committee Report on Patent Law Issues

In the meantime, taking note of the extensive debate in both Houses of Parliament on two main issues when the Patent (Amendment) Bill 2005 was introduced, the Minister of Commerce and Industry commissioned a Technical Expert Group on Patent Law Issues under the chairmanship of the charismatic Dr RA Mashelkar, then Director of the Council for Scientific and Industrial Relations (CSIR), on 5th April 2005. (Dr Mashelkar retired on 31st December 2006.) The two terms of reference for the five-member group, also known as the Mashelkar Committee, were:

- whether it would be TRIPs compatible to limit the grant of patent for pharmaceutical substances to new chemical entities (NCEs) or to new medical entities (NMEs) involving one or more inventive steps; and
- whether it would be TRIPs compatible to

exclude micro-organisms from patentability.

Adopting a consultative approach, the Mashelkar Committee sought input from various stakeholders, including industry associations, non-governmental organisations and patent attorneys, in relation to various factors such as public accessibility to affordable medicines, current R&D capabilities of Indian industries etc. On 28th December 2006 the Committee submitted its report, which is now available on the Indian Patent Office website at www.patentoffice.nic.in.

With regard to issues relevant to this article – the granting of patents to NCEs and NMEs – the Mashelkar Committee Report concluded as follows:

- It would not be TRIPs compliant to limit the granting of patents for pharmaceutical substance to NCEs only. Paragraph 5.7 of the report points out that Article 1 of the TRIPs Agreement requires compliance with the Agreement’s provisions, while compliance with TRIPs-plus provisions is optional. Thus, limiting the granting of patents for pharmaceutical substances to NCEs only and excluding new forms of crystals, polymorphs etc – even if they satisfy the basic patentability criteria – would not be consistent with India’s TRIPs obligations.
- It is important to distinguish the “evergreening” of patents from incremental inventions. The report concludes that, even in the Indian context, incremental inventions – even in the field of pharmaceuticals – are patentable. Paragraph 5.10 of the report states: “Incremental developments ought to be encouraged by the Indian Patent Regime.”
- The report recommends the formulation of detailed guidelines for the examination of pharmaceutical inventions in order to prevent “[t]he remotest possibility of granting frivolous patents”.

Although the report aims to clarify understanding of “pharmaceutical substances”, there is no mention of new forms of known substances insofar as other chemicals, such as agricultural chemicals, are concerned. It is only by implication, in reading Section 5.2 of the report, that it may be assumed that NCEs would refer also to agricultural chemicals.

It is hoped that the patent examination guidelines will take account of inventions relating to all chemical entities, rather than just “pharmaceutical substances”.

Other debates – patentability of micro-organisms

Other debates are also ongoing between patent agents and examiners on the interpretation of the statutes. One of these issues, also addressed by the Mashelkar Committee Report, is whether a micro-organism is a patentable invention.

Until 2002, the Patent Office as a matter of practice granted patents only to non-living, tangible inventions that fulfilled the patentability criteria, even though the Patent Act imposed no such limitation. In 2002, however, before the 2002 amendments came into force, the Calcutta High Court passed a landmark judgment setting new standards of patentability for biotechnological inventions. The applicant, *Dimminaco AG*, had applied for a “process for the preparation of Bursitis vaccine”, which was rejected by the Patent Office on the grounds that the end product was a live vaccine and therefore was not a patentable substance under Section 2(1)(j). On appeal against the Controller’s order, in *Dimminaco AG v Controller of Patents* (AID No 1/2001), the Calcutta High Court held that there is no statutory bar to the patentability of a process even if it contains a living organism, provided the process fulfils the patentability criteria.

Fourteen months later, on 20th May 2003, the Patents (Amendment) Act 2002 came into force and the amended Section 3(j) brought micro-organisms within the scope of patentability. This sowed the seeds for a raging debate. The amended Section 3(j) states that “plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals” are not patentable.

Industry, academics and patent lawyers have since been debating on various issues, ranging from how to define “micro-organism” from a patent perspective, to what constitutes a patentable invention in case of a micro-organism, to whether a micro-organism *per se* is patentable.

The Mashelkar Committee Report examines the various definitions of micro-organism and the patentability criteria followed in progressive patent jurisdictions, including European countries, Japan, Korea, China and the US, and then reviews Indian R&D in the biotechnology sector.

A recent Ernst & Young report ranking India third in the Asia-Pacific region (after Japan and Korea) in terms of the number of

biotech companies, and confirming that India’s 280 biotech companies have generated US\$1.5 billion in revenue, indicates that India’s current share of the global market is just under 2%. According to estimates, the Indian biotech sector has been growing at a rate of 35% to 40% per annum for the last three years and revenues are projected to reach US\$5 billion by 2010.

The Mashelkar Committee Report appears to have kept these statistics and projections in sight while concluding that the exclusion of micro-organisms from patent protection would violate the TRIPs Agreement. The Report also stressed that, given India’s abundant biodiversity, it would be “[i]n our interest to document, protect and modify new micro-organisms isolated from various parts of our country and find their new and improved industrial uses”.

However, the Report also recommended the formulation of strict guidelines for the examination of patent applications pertaining to micro-organisms “from the point of view of substantial human intervention and utility”; this appears to accord with the requirements in other progressive countries.

Conclusion

These are uncertain times for the India pharma sector. While the market is buoyant, reportedly generating US\$5.2 billion in revenue, it accounts for just 1% in value and 8% in volume of the global pharma industry. India manufactures about 400 bulk drugs and around 60,000 formulations which are distributed by 500,000 chemists in India. However, per-capita drug expenditure is very low when compared to the rest of the world.

The Indian pharma sector has also been making its presence felt globally. Cases in point are the US\$570 million acquisition of German company Betapharm by Dr Reddy’s, and Matrix Laboratories’ acquisition of Belgian company Docpharma for US\$263 million.

Another important milestone is that a small number of companies are now moving into original research. A balanced patent protection regime that distinguishes incremental inventions from the “evergreening” of patents is thus needed now more than ever before. Such balanced patent protection would serve as an incentive to Indian companies to develop new pharmaceutical and biotechnological inventions, which will prove to be a bonus not only for the pharmaceutical industry but also to society at large – the ultimate beneficiary.



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