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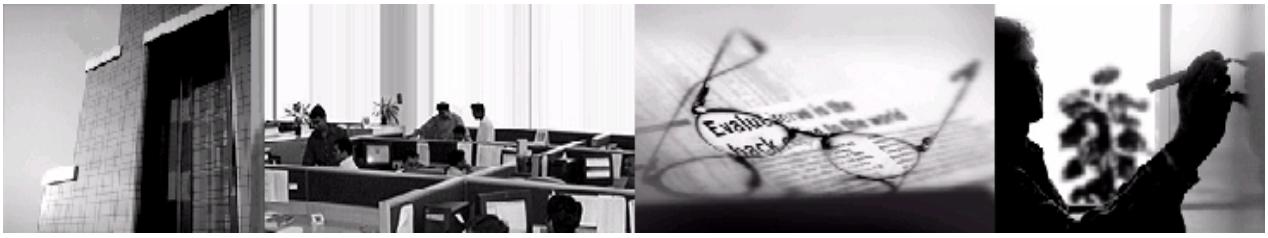

The Patents (Amendment) Ordinance, 2004 in India -- Evalueserve Analysis

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Introduction

The Indian Government issued the Patents (Amendment) Ordinance, 2004 on 26 December 2004, which has brought significant amendments in the Indian Patent law. The Ordinance was issued in the light of the completion of the extended timeline allowed to India (December 2004), conforming to obligations under the TRIPS agreement. It will, however, have to be approved by both houses of the Indian Parliament (in the next parliament session in February 2005), or it will lapse six months after it was issued.

The objective of this report is to analyse the major implications of the amendments, particularly those pertaining to the following:

1. Introduction of a product patent regime for medicines and drugs
2. Patentability of computer software inventions
3. Foreign filing of patent applications by Indian residents

The report analyses the implications of the product patent regime for multinational pharmaceutical companies. In addition, it highlights certain ambiguities and open-ended questions arising from the provisions relating to the patentability of computer software inventions and foreign filing of patent applications by Indian residents. The report also stresses the need for specific guidelines to resolve these issues.

This report has been organised into three sections:

1. The first section analyses the implications of the product patent regime for multinational pharmaceutical companies, related to the following:
   1.1. Size of the existing market (that India represents)
   1.2. Research & Development (talent and costs)
   1.3. Manufacturing and licensing opportunities
   1.4. Marketing tie-ups
2. The second section analyses the amendment pertaining to the patentability of software inventions in India. According to Evalueserve analysis, the ordinance has widened the scope of patentability for computer software. However, there is also considerable ambiguity. Therefore, concrete guidelines should be laid down by the Government, which will address many open-ended issues.
3. The third section analyses the implication of the amendment in Section 39, which has introduced strict restrictions on Indian residents seeking to file abroad.

1 Product Patent Regime in India

1.1 The Amendment

According to the Patents (Amendment) Ordinance, 2004, product patenting has been introduced for pharmaceuticals, food and chemicals, effective from 1 January 2005.

In its current form, the ordinance has provisions for applicants who wish to obtain patent protection on almost every aspect of drug development -- from molecules and micro-organisms to processes and step-wise sequences (for any innovation).

1.2 Implications for Pharmaceutical Multinational Corporations (MNCs)

The product patent regime has significant implications for the healthcare sector in India. These pertain to the following four key factors:

Size of the existing market (that India represents)

Research & Development (talent and costs)

Manufacturing and licensing opportunities

Marketing tie-ups

1.2.1 Market Size and Penetration

The Indian pharmaceutical market is characterised by two dominant factors: its vast size and low penetration.

India, home to nearly 16 percent of the total world population, represents a large potential market for pharmaceutical multinationals. Estimated at USD 5 billion (end 2004), and growing at 8-9 percent annually, India's pharmaceutical Industry represents roughly 1.25 percent (by value) of the global pharmaceutical sector. Further, its penetration level is merely 30 percent, with up to 70 percent of its population having no access to medical care.

This represents a large untapped market, with low penetration, which can be captured by multinationals through volume sales and realistic pricing.

1.2.1.1 Expanding Opportunities in the Health Insurance Sector

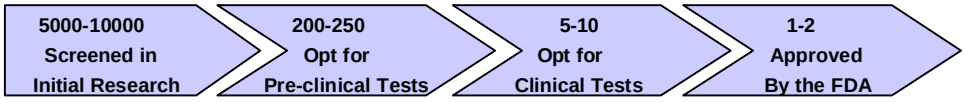
The eventual, inevitable increase in drug prices (and healthcare costs) will result in people enrolling for comprehensive healthcare insurance services. The Indian middle class, an estimated 312 million, forms the most attractive segment of the target population.

As of 2000, only 3.5 million people were covered by health insurance in India, and the healthcare insurance sector was reported at USD 13 million, growing at 16 percent annually. The current penetration of medical insurance is low in India, reported between 1.95-3 percent.

This represents a strong opportunity for multinational insurance and managed healthcare firms (including HMOs and customised healthcare management firms) to enter India, either independently or through agreements with pharma multinationals. In India, low premia can result in large numbers of subscribers, generating profits through volume sales.

However, unfriendly regulations, high initial investments, and the lack of awareness about insurance among the majority of the population may not allow significant growth in this sector.

1.2.2 Research and Development



Research & Development (R&D) forms the key thrust area in the search for innovations to cure and heal. The benefits offered by India can be leveraged by multinationals across the field of Developmental Studies.

1.2.2.1 Developmental Studies

It takes between USD 800-USD 900 million to create a new drug. Effectively, the split between Research and Development for drugs is estimated as 30:70.

Further, between 55-60 percent of the development cost can be attributed to clinical trials. It takes between USD 350-USD 500 million for a New Chemical Entity (NCE) to pass through all the stages of clinical trails and reach the market.

Research indicates that conducting drug-related studies in India can lower drug discovery costs by as much as one-tenth of current values.

1.2.2.1.1 Pre-clinical and Clinical Trials

The current regime will grant “patent safety” to multinationals, allowing them to invest in India’s Contract Research Organizations (CRO). Indian companies represent a noteworthy commercial opportunity for carrying out pre-clinical and "proof of concept" studies and research for NCEs. Clinical trials, if they are conducted in India, can reduce trial costs significantly.

Apart from cost-related savings, India can offer other advantages, enumerated in Table 1.

Table 1: The India Advantage

Advantage(s) Offered	Premise
Cost Benefits	Conducting drug-related studies in India can lower drug discovery costs to as much as one-tenth of current expenditure.
Biodiversity	India, being multi-ethnic, offers variations in drug interactions, symptomatic pathology and endemic diseases.
Low Enrolment Time	India’s population density promotes rapid recruitment. This can translate into less time spent on trials and overall development
Indian CRO Industry	The Indian CRO industry comprises globally recognised infrastructure and professionals.
Talent Pool	It is acknowledged globally as offering the highest return in terms of intellectual capital per US dollar invested.

Source: Evalueserve Research

1.2.3 Manufacturing and Licensing Opportunities

The product patent regime will open up the lucrative Indian market for multinationals. These multinationals can set up operations either through licensed agreements, mergers and acquisitions (M&A), or a mixture of both.

1.2.3.1 Mergers and Acquisitions

India has over 30, 000 pharmaceutical business units. Over 80 percent of these players cannot make large independent investments in R&D. With the product patent regime in place, many Indian companies will be restricted to operating in the overcrowded generics market in the future. Some of these companies will either perish or get acquired by larger players. Multinationals, however, have the opportunity of setting up low-cost operations through an equity stake or the control route. They can harness smaller units as a low-cost manufacturing base for global sales and generate higher margins.

1.2.3.2 Licensed Production

MNCs can also tie up with Indian pharmaceutical companies for licensed manufacturing of branded and generics, and use them as a sourcing destination for international markets. The product patent regime effectively eliminates the potential for copycat production, so MNCs can tie up with Indian players, without fear of reverse engineered generics flooding the market during the patent tenure.

1.2.4 Marketing Tie-ups

The creation of marketing and sales channels is usually a long, expensive and arduous task. MNCs can not only benefit from low manufacturing costs in India, but also leverage Indian players' existing sales and marketing channels/workforce to achieve market shares at significantly lower costs. This would further reduce the time to market for MNCs' drugs/ products and ensure a deeper reach for them.

1.3 Conclusion

The Indian market represents a unique proposition for pharmaceutical multinationals that temper their ambitions with realism.

These multinationals need to focus on realistic pricing and rely on volume sales to capture the vast market (with its potential size being only a little larger than that of the pharmaceutical market in France or Germany) and deliver profits to their doorsteps, at least for the next 20 years.

2 Patentability of Computer Programs

2.1 The Amendment

The Patents (Amendment) Ordinance, 2004 has amended the provision related to the patentability of computer programs. As per amended Section 3(k) of the Patents Ordinance 2004, computer programs per se continue to be non-patentable. However, a computer program is patentable in the following forms:

1. A computer program that has a technical application in industry OR

2. A computer program in combination with hardware

Earlier, although computer programs *per se* were non-patentable, there were certain cases in which software, in combination with hardware, was considered patentable. Section 1.3.8 of the Manual of Patent Practice and Procedure (of the Indian Patent Office) stated that software, in combination with hardware, could be considered patentable only if the software necessitated special adaptation or modification of a computer's hardware and organization. For example, if the format of a program or the nature of the record medium (tape, disc, etc.) required some 'non-standard' adaptation to the computer, the program in combination with the computer, could be considered patentable.

2.2 Ambiguous Issues

According to one interpretation of the amendment in Section 3(k), the combination of software and hardware is considered patentable if it can be proven that it has technical application. This interpretation implies that a wider scope of patentability has been allowed for inventions combining software and hardware. The requirement of some non-standard adaptation to the hardware (as required under the previous law) seems to have been done away with. It can now be considered that any combination of software and hardware that has a technical application will also be patentable, irrespective of any non-standard adaptation to the hardware.

According to another interpretation of the amendment, there are three main issues that can be the subject of discussion in relation to amended Section 3(k):

a) Firstly, the use of the term 'OR' introduces ambiguity to the question of patentability of computer programs. It can be implied that Section 3(k), in its present form, allows patentability of *pure software (computer program)* if it is proven to have some technical application, for example, a computer program that improves the quality of a digital image may now be patentable, since its technical application lies in the improvement of the quality of digital photographs.

b) Secondly, the exact scope of the patentability of inventions comprising a combination of software and hardware is not very clear. It is not clear whether all combinations of software and hardware are patentable. For instance, in order for an invention to be deemed patentable, it is not clear where the novelty of the invention should lie in (i) software, (ii) hardware, (iii) software as well as hardware, or (iv) any of the software and hardware. As an example, consider a case where a novel program is run on a known computer to cause the computer to perform a novel functionality. In this case, the patent drafter may claim the steps comprising the program (software) as the steps carried out by a computer (hardware) to perform a novel function. This means that the drafter can claim that it is a combination of software and hardware. However, the amendment does not make it clear if such a case comes under the purview of a patentable invention.

c) Thirdly, the interpretation of the term "technical application" is not very clear. Criteria for judging whether a software invention has a "technical application" need to be clearly defined. The European Commission's directive regarding the patentability of software inventions is pertinent in this regard. As per the directive, a computer-implemented invention is patentable only if the invention makes a significant *technical contribution* to the existing state of art. The directive states that computer-implemented inventions in which computer programs do not produce any technical effect beyond normal physical interactions between the program and the computing device are not patentable.

2.3 Conclusion

By the introduction of these provisions, India has moved a few steps towards patenting computer software. However, a defined set of policies and guidelines for patenting software should emerge, which will resolve ambiguities and open-ended issues.

3 Foreign Filing by Indian Applicants

3.1 The Amendment

According to the patent laws of many countries, permission has to be obtained for domestic inventions that are to be patented in foreign countries. For instance, the US patent law requires a foreign filing license to be obtained before a patent can be filed outside the US for any invention made in the US, unless six months have lapsed from the US filing of the patent application. Such provisions are included in national laws to safeguard inventions that pertain to countries' national defense and security.

A similar provision has been introduced in Section 39 of the Indian Patents Act by the Patents (Amendment) Ordinance, 2004 (this provision was deleted from the Patents Act in 1999) The following is a brief analysis of Section 39 and its corresponding rules (Rule 71 as amended by the Patents (Amendment) Rules, 2005:

1. Section 39 is applicable to 'a person resident in India'.
2. There are two options available to 'a person resident in India' who wants to file a patent application outside India:
    A. Option 1 -- Obtain a written permit from the Controller before applying for a patent outside India:
        i. The request for the written permit should be made on Form 25 along with the requisite fee. The fee is INR 1000, if the applicant is an individual. If the applicant is a company or any other entity, the fee is INR 4000.
        ii. It is required that the details of the patent application (if the applicant has already made the application in India) are submitted in the request, OR
        iii. If the applicant making the request has not already applied for a patent in India, a 'brief description' of the invention is to be submitted along with the request.
        iv. As per rule 71 (ii), the Controller shall ordinarily dispose off such a request within three months (this implies that it can take more time in certain cases).
    B. Option 2 -- File for a patent application in India. If no directions pertaining to secrecy are received in respect of the patent application within six weeks of the filing date, the application can be filed outside India. In other words, the applicant should file outside India only after a lapse of six weeks from the Indian filing, only if no secrecy directions are received from the Controller. If these directions are received within six weeks, the patent application cannot be filed outside India, till the time the secrecy directions are revoked by the Controller. Secrecy directions are issued in respect of patent applications for inventions that are deemed relevant for defense purposes.

3.2 Open-ended Issues

The discussion of the provisions, given above, lead to the following questions, the answers to which are not clear in the absence of definite guidelines from the government and the Patent Office:

1. What is the exact definition of 'a person resident in India'?
    a. No definition of this term has been given in the Patents Act or the latest Ordinance of 2004. The Patents Act simply defines the term 'person' to include the Government {Section 2(1)(s)}
    b. According to the Indian law, an applicant for a patent can be an inventor as well as a company. Therefore, the phrase, 'a person resident in India', can refer to a resident individual or a resident company. This implies that an

Indian company (registered and, with operations in India) will also require permission to file abroad.

2. What is the implication of the words *"cause to be made"*? The provision in Section 39 states that no person resident in India shall make or *"cause to be made"* any application outside India without a written permit.
    a. It seems that Section 39 will be applicable in the case of more than one inventor, who jointly wants to apply for a patent outside India, if only one of them is resident in India. In another instance, it seems a permit will be required if an Indian inventor assigns the invention to a foreign company, to file a patent application outside India.
3. What is the meaning of 'Brief Description' in the request form (Form 25)? Is it a requirement that the request in Form 25 should be accompanied with a brief description of the invention? It is still unclear what is meant by the requirement of the submission of a brief description. If this implies that an Abstract or Summary of the invention can be submitted, then inventors will benefit, since a request can be made while a formal patent application is being prepared for filing.

3.3 Conclusion

The above provisions are aimed at guarding India's national security interests. However, they are likely to slow down the patent-filing activity of Indian applicants in foreign countries. It should be the endeavour of the Indian Patent Office that no-objection applications are processed without long-drawn bureaucratic processes. In addition, specific guidelines should emerge in order to address the above-mentioned questions.

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