Filings in mailbox against "basic principles" would not qualify for patent in India even after 2005'

With India poised to enter the product patent regime — with the compliance of TRIPS agreement — by the year 2005, the country's pharmaceutical segment is now most concerned about various implications of TRIPS, many of which is still not apparent and also ambiguous about various provisions in the IPR law.

While research-based companies are concerned about ensuring protection for their intellectual property, others are worried about safeguarding their existing product profile. However, formulating strong and enforceable IPR laws in harmony with a workable framework for accessibility and affordability of the country is going to be a challenge for the government, emphasises **Dr. Prabuddha Ganguli, *Leading IPR Expert & Consultant*** in an exclusive interview with **C H Unnikrishnan** of ***Chronicle Pharmabiz***

Among all sectors, the pharmaceutical sector appears to be most affected by the TRIPS agreement. What is your view?

TRIPS agreement does not differentiate between the various sectors. In fact one of the main contentions of TRIPS is embodied in Article 27 (1) which states "Patents shall be available to any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application." Further it states "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

This makes it amply clear that there is no differentiation that is contemplated or brought about by the TRIPS agreement. The key challenge is therefore in formulating strong and enforceable IPR laws in harmony with" workable frameworks for accessibility and affordability. This is true for all sectors that influence the quality of our lives. It should be appreciated that all aspects of healthcare are some of key concerns of the public and hence this field draws more attention than others in most debates on IPR.

As per the compliance timetable what has India done so far?

As India is a member of the WTO, she is bound to comply with the requirements of the TRIPS agreement including the timetable set by it to introduce the new legislations with respect to IPR. In this context, India introduced the first Patent Amendment to the Indian Patent Act 1970 in April 1999. Two key aspects of this amendment were the " provision for a mailbox" to file product patents in India with effect from January 1, 1995 and the "provision for EMR" for products related to Drugs, Pharmaceuticals And Agrochemicals with effect from January 1, 1995.

As we all know that the second patents amendment to the Indian Patents Act 1970 was also passed by the two houses of the parliament and it got the assent of the president. We therefore have a new Act in place but this is still not in force, as the rules have not yet in place. The details of this were covered in an article I wrote in the *Chronicle Pharmabiz* issue dated December 26, 2002.

What is the implication of the first amendment to the Indian Patents Act 1970 especially with respect to the pharmaceutical sector?

The implication of the 1st Amendment to the Patents Act 1970 is that any product patent filings in the "mailbox" should satisfy the basic principles of patents i.e. these should not have appeared in the public domain any where in the world prior to January 1, 1995 as it would then constitute prior art" and therefore would not qualify for a patent in India even after 2005 when the Patent Law in India is amended to allow the granting of product patents in India.

This aspect is based on Art. 70(3) of TRIPS which states "the member countries of TRIPS shall have no obligation to restore protection to subject matter which on the date of GATT agreement has fallen into the public domain".

This therefore makes it amply clear that one should study the dates on which various patent applications got published or were put on sale in any part of the world prior to 1995 to identify the molecules that might still qualify for product patents in India after January 1, 2005.

Various experts have recently told us that several new drugs that have been introduced in the Indian market by Indian companies may have to be withdrawn after the product patents regime comes into force in India. What would be considered as infringement of patents in India vis-à-vis such molecules?

There cannot be any general answer to such a question. We have to look into the molecules on a case-by case basis. General statements could be grossly misleading.

Let us consider a set of drugs such as rofecoxib, ofloxacin, clopidegrel, domperidone, omeprazole, pantaprazole, cefixime, proglitazone, sildenafil citrate, and rosiglitazone. These have been introduced into the Indian market by various drug companies. What would be their fate?

I would analyse them on the basis of their dates of their patent filings and their publication history. According to the publication dates of the patent applications covering the 10 products mentioned by you 9 (except for Rofecoxib) of the products have come into public domain much before 1.1. 1995.

Therefore, the nine products cannot be considered for product patents in India after 2005. More importantly, they cannot be considered for product patents even if the inventor companies have filed their patents in the mailbox after January 1, 1995. Therefore one need not get concerned about these 9 products.

What about Rofecoxib?

The PCT application of Rofecoxib was published in the PCT Gazette on January 5, 1995. Therefore if Merck had to file a product patent application in the "mailbox" in India it should have done so on a day from January 1 to January 4h 1995. This aspect needs to be investigated from the gazette of India records

What is it like consulting in the field of IPR?

It is interesting as we tackle live problems for the academic institutions, industry, governments and international organizations such as WIPO, etc. Our work includes integrating IPR into innovation and business strategies, preparing sector specific IPR status reports, training of personnel to manage IPR in their organisations, strategic use of IPR information. ◆

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