Exclusive Marketing Rights — Background and Their Implications

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Presents the background of the Agreement of Trade-Related Intellectual Property Rights. Describes transition period, and various amendments in Patents Act. The salient features of Patents (Amendment) Act, 1999 are given in detail. Provisions of exclusive marketing rights (EMR) and their implications are explained in detail, and EMR fee schedule is provided.

The Uruguay Round of multilateral trade negotiation was launched at Punta Del Este in Uruguay in September 1986 at a special session of the General Agreement on Trade and Tariff (GATT) contracting parties held at Ministerial level. These negotiations were the most ambitious and complex, as negotiations covered not only the traditional GATT subjects such as tariff and non-tariff measures and improvement of GATT rules and disciplines on subsidies, safeguards, etc. but also extended to new areas not dealt with by GATT such as Trade-related Aspects of Intellectual Property Rights (TRIPS), Trade-Related Investment Measures (TRIMS) and Trade in Services.

On 15 April 1994, India along 117 nations signed the GATT Agreement at Marrakesh in Morocco establishing the World Trade Organization (WTO) and it came into force on 01 January 1995 (replacing MTO of 1993). Thus, the Agreement on TRIPS is a part of the WTO Agreements arising out of the results of the Uruguay Round of multilateral trade negotiations. The Agreement lays down minimum standard of protection of intellectual property rights (IPR) to be followed by WTO members (on 1 December 1999 WTO had 135 nations as its members). It covers minimum standards on eight IPR. The forms of IPR covered by TRIPS are: copyright, trademarks, geographical indications, industrial designs, layout designs (topographies) of integrated circuits, undisclosed information, control of anti-competitive practices in contractual licences, and patents.
Patents

Members are required to make patents available for any invention whether product or process, in all fields of technology without discrimination, subject to normal tests of novelty, inventiveness and industrial application. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced. However, three exceptions to the basic rule on patentability are suggested and members may exclude from patentability the following:

1. Inventions contrary to order of public or morality; and this includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection or order of public or morality.

2. Diagnostic, therapeutic and surgical methods for treatment of humans or animals.

3. Plants and animals other than microorganisms and essentially biological processes for production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties must provide an effective *sui generis* system of protection. Moreover, the whole provision is subject to review four years after entry into force of the Agreement.

Transitional Period

Under these arrangements, developed countries have had to meet their obligation under the Agreement by one year, i.e. 01 January 1996, while developing countries got additional four years, i.e. time up to 01 January 2000. In addition, where developing countries did not extend product patent protection to certain areas of technologies as on 01.01.1995, they could delay the application on the provisions on product patents to such areas of technology up to 01 January 2005.

Under the Agreement on TRIPS, India has availed of transition period for meeting its obligations. As per this transition period, India had to bring its intellectual property laws in conformity with the TRIPS Agreement by 01 January 2000. This would mean making some changes in the Patents Act, 1970, the Design Act 1911, and the Trade and Merchandise Marks Act 1958. In addition, laws relating to geographical indications, layout designs of integrated circuits, and enforcement provisions of the TRIPS Agreement would also need to be implemented within this period.

In respect of areas of technologies where product patents are not available in the current Indian patent law, India has time up to 01 January 2005 to provide for grant of product patents. India does not provide product patent protection in respect of food, drug and substances prepared by chemical processes at present, such protection have to be made available by 01 January 2005. As per the TRIPS Agreement, however, in the intervening period applications for product patents in the area of pharmaceutical, and agricultural chemical products will have to be accepted and put in a ‘mailbox’ to be opened after 01 January 2005, but provide exclusive market-
ing rights (EMR) for five years in the interim subject to same stipulated conditions.

Amendments in Patents Act

With a view to meeting India’s obligations under the above said Agreement while safeguarding its interest, it has become necessary to amend the Patents Act, 1970 in conformity with the obligations under Articles 70(8) and 70(9) of TRIPS. As the Parliament was not in session, the President of India was pleased to promulgate an ordinance, namely, the Patents (Amendment) Ordinance, 1994 on 31 December 1994 making it in force on 1 January 1995.

By virtue of this Patents (Amendment) Ordinance 1994, it was proposed to amend the existing sections 5, 40, 64 and 118 and omission of section 39 of the Patents Act, 1970. Further, there was a proposal of insertion of a new chapter IV A, consisting of new sections 24A, 24B, 24C, 24D, 24E and 24F in the existing Patents Act, 1970. The above said amendments in the Patents Act, 1970 had been approved by Lok Sabha but Rajya Sabha referred the bill to the Select Committee. Thereafter Parliament was dissolved and the Ordinance issued in December 1994 lapsed. In the mean time, US took the matter to WTO Dispute Settlement Body. The Panel and Appellate Board ruled that legal means for the mailbox and EMR are required for predictability and certainty. India got time up to 19 April 1999 to implement the decision.

The Government of India reissued the Patents (Amendment) Ordinance, 1994, with some amendments of the previous text on 08 January 1999, such as insertion of new section 157A and the said amendment ordinance is referred to as The Patents (Amendment) Ordinance, 1999. Prior to this, the Government of India introduced the Patents Amendment Bill, 1998 in December 1998 in the Rajya Sabha where it passed but could not be introduced into the Lok Sabha in December 1998. The Bill was introduced in the Lok Sabha in March 1999 and was passed, since there were minor amendments in the Bill placed in Lok Sabha, it was again reintroduced in Rajya Sabha, there also it was passed.

Thus, as the Patents (Amendment) Act, 1999 of 26 March 1999, promulgated on 8 January 1999 as Patents (Amendment) Ordinance, 1999, came into force having effect from 01 January 1995.

Salient Features

Salient features of the Act are:

1. Keeping in view of the obligation under TRIPS Agreement;
   (a) Section 5 of the principal Act has been amended to permit filing of application for patent in the field of pharmaceuticals and agrochemical products.
   (b) Provisions regarding grant of EMR has been included at chapter IV A under sections 24A to 24F.

2. Keeping in view of the public interest in India:
   (a) Section 39 of the principal Act has been omitted to remove hindrance to Indian applicants for filing the patent applications in foreign countries.
   (b) Provision of compulsory licence has been introduced on the EMR.
   (c) Special provision for selling or distributing in public interest by the Government of India has been incorporated.
   (d) Provision for price fixation in public interest by the Government of India has been incorporated.
(c) Provision regarding protection of security of India has been included.

Now to allow an application for grant of exclusive right to sell or distribute the article or substance in India on application for patent filed under section 5(2) of the Act, the following are the conditions under section 24A of the Act:

(a) Application for article or substance shall not be examined under section 12 of the Act till 31 December 2004, the same shall be examined only whether the inventions is not an invention within the meaning of the Act, in terms of section 3 or the invention is an invention for which patent cannot be granted in terms of section 4 of the Act.

(b) The condition for grant of EMR under section 24B of the Act to invention originated in India or in a country other than India and before filing such a claim.

i) Filed an application for same invention claiming identical article or substance in a convention country on or after 01 January 1995.

ii) Corresponding applicaton under section 5(2) of the Act, claiming identical article or substance filed in India on or after 01 January 1995.

iii) Patent to the above referred application should be granted in convention country on or after the date of filing application under section 5(2) of the Act.

(iv) The marketing approval to sell or distribute the article or substance should be granted in India by appropriate authority specified in this behalf by the Government of India.

On satisfying the above five conditions and on positive result of examination under sections 3 and 4 of the Act, EMR shall be granted for a period of five years from the date of grant (on form 28).

(c) The condition for grant of EMR under section 24 of the Act, to invention originated in India, and before filing such a claim.

i) Filed an application for patent on or before 01 January 1995, for method or process of manufacture for the invention relating to article or substance.

ii) Filed an application for patent on or after 01 January 1995, under section 5(2) claiming article or substance identical to that obtainable from above referred method or process of manufacture.

iii) Patent to above referred application for method or process should be granted in India on or after the date of filing application under section 5(2) of the Act.

iv) The marketing approval to sell or distribute the article or substance should be granted in India by appropriate authority specified in this behalf by the Government of India.

On satisfying the above four conditions and on positive result of examination of application for article or substance under sections 3 and 4 of the Act, EMR shall be granted for a period of five years from the date of grant (on form 28).
The EMR fee schedule is presented in Table 1.

It may be noted that provision to curb the abuse of EMR has also been incorporated in the Patents (Amendment) Act, 1999, such as under section 24C of the Act, a provision for compulsory licence shall apply in relation to an exclusive right to sell or distribute under section 24B as they apply to a right under a patent in the principle Act. The application for compulsory licence can be filed after two years from the date of approval of EMR. Under section 24D of the Act, the Government of India in public interest is also empowered to sell or distribute the article or substance by itself or through any person authorized in writing on its behalf and to control the price of the article or substance, as determined by an authority specified by it in its behalf. Here needless to mention that the TRIPS Agreement does not specifically prohibit the use of price control measures.

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<td>8</td>
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Under section 24E of the Act all suits relating to infringement of a right under section 24B shall have same provision as the suits concerning infringement of patent under the principal Act.

The section 24F of the Act deals with the condition that the Government of India and its officers shall not be liable in any way to warrant the validity of grant of any exclusive right to sell or distribute by virtue of examination and investigation under this Act.

Since section 39 of the Act has been omitted, amendment of sections 40, 64 and 118 were necessary as reference of section 39 was there.

A new section 157A has been incorporated for protection of security of India, empowering the Government of India to take action including the revocation of any patent which it considers necessary in the interest of security of India, of course it shall be necessary to issue a notification in the official gazette declaring its intention to take such action.

**Implications of EMR Provisions**

Till date only one application for grant of EMR has been filed in India and the same is under processing. The number of applications for patent filed under section 5(2) of the Act, are about 3,500 lying in the mailbox from 01 January 1995. As such, effects of EMR on industry and indigenous R&D are yet to be seen. The apprehension of the public that prices of drugs have gone up due to introduction of EMR by virtue of th Patents (Amendment) Act, 1999, appears to be baseless as the TRIPS Agreement provides that neither the drugs that are available in the market nor the drugs whose process patent are already published can be protected by patents and EMR in India. Another apprehension of industry and public that applicants from abroad may apply for patents and EMR for article or substance of new formulation, change in usage form, dosage form and combination thereof are also appear to be baseless as under section 3(e) of the principal Act, the inventions relating to basic drugs related formulation are not patentable, moreover, under section 3(d) of the principal Act, the invention relating to change in dosage form, usage form and combination thereof are not patentable. As said earlier, the grant of EMR on article or substance under section 24B, depends on positive result of examination under sections 3 and 4 of the principal Act.

There may be a price rise only in respect of drugs which are patented in India after 01 January 1995 because it is universal truth that the inventors also deserves material benefit for their achievements for which they have normally spent time and money, and for further investment in R&D activities. However, the Government of India is empowered to monitor the situation under the Act. So, we can rest assured that the Indian patients will not be deprived of the treatment with new drugs.

AS per author’s understanding the substantial growth of Indian pharmaceutical industry during the past 25 years has been possible entirely due to its excellent performance in “applied” R&D, i.e. development of process, technologies, product formulations for already known active ingredients. It is disheartening to note that the “basic” R&D is not existing to the tune it should be considering the potential of our country. It is now essential that the pharmaceutical industry, to survive and to contribute to the economic growth, has to conduct
and invest in basic R&D and take steps to build up the infrastructure.

References

Following references were consulted for preparing the article:

3 Patents Act, 1970.
4 Patents (Amendment) Act, 1999.
5 Patents Rules, 1972.
6 Patents (Amendment) Rules, 1999.
7 The Gazette of India, Part III, Section 2, 8 April 2000.