# THE IMPLICATIONS OF THE PATENTS (AMENDMENT) ORDINANCE, 1999

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## Foreword

As an original contracting party to the 1947 General Agreement on Tariffs and Trade (GATT), it was logical for India to become a founder member of the World Trade Organization (WTO) which replaced GATT. Nonetheless, it was only after an intense debate in the early 1970s that a consensus emerged that it would be in India's interest to be part of a multilateral trade regime which sought to provide transparent systems of dispute settlement. An important obligation that India took upon itself was to conform to the WTO agreement on intellectual property rights protection by signing the TRIPS Agreement in 1995.

The TRIPS Agreement has been the subject of a great deal of controversy in the country, dividing political opinion and generating a number of concerns about the patenting process, especially with respect to medicines. Unfortunately, much of the debate has had to take place with limited information and an incomplete understanding of the many clauses of this complex treaty. Under the TRIPS Agreement India has agreed to accept applications for product patents of pharmaceuticals and agro-chemicals from January 1, 1995 onwards. The applications will be received in a 'mailbox' and will be examined only with effect from January 1, 2005. Further, the TRIPS Agreement also makes it obligatory for India to grant Exclusive Marketing Rights to pharmaceuticals and agro-chemicals which have been given product patents and marketing approval in another member-country of the WTO.

The Patents (Amendment) Ordinance, 1999 will have to be ratified by a legislative act. The bill seeking to amend the Patents Act is before Parliament. To facilitate an informed debate, the Indian Council for Research on International Economic Relations (ICRIER), New Delhi, requested Mr. A.V. Ganesan, Advisor to ICRIER on WTO related issues and former Commerce Secretary and one of India's most distinguished civil servants, to write a paper setting out the issues that arise in the context of the Patents Amendment Ordinance, 1999, i.e. the issue of the mail box and EMRs.

This paper was discussed at a seminar organised by ICRIER on February 16, 1999, which was presided over by the Director-General of the Council for Scientific and Industrial Research (CSIR), Dr R A Mashelkar and attended by several Members of Parliament, experts in the field and eminent journalists. Mr Ganesan's paper and a report of the proceedings of the seminar are presented here to facilitate a wider public debate.

Mr Ganesan and Dr Mashelkar reaffirmed that the protection of intellectual property will serve India's national interest and the interests of our scientists, technologists, industrialists and researchers if we learn to derive the benefits of the rights we have secured and put in place the legal and institutional instruments that will enable us to do so. The Patents (Amendment) Bill, 1999, is one small step in this process.

Isher Judge Ahluwalia
Director & Chief Executive
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## Executive Summary

Stated simply, intellectual property refers to a creation of the human mind that is of value to the society. Intellectual property rights (IPR) are rights granted by the State to persons over creations of their mind. The TRIPS Agreement of the WTO covers nine categories of intellectual property

- copyright and related rights,
- trademarks including services marks,
- geographical indications,
- industrial designs,
- lay-out designs of integrated circuits,
- trade secrets,
- patents,
- patenting of micro-organisms, and
- new plant varieties (i.e., seeds and other propagating material).

The Agreement lays down the minimum levels of substantive norms and standards to be followed by member countries for the protection of these intellectual property rights as well as for their enforcement.

Our existing or proposed laws and regulations in respect of the first six categories of intellectual property are largely in consonance with the standards of protection incorporated

in the TRIPS Agreement. Our enforcement standards and judicial pronouncements are also on a par with those of the industrialised countries.

Our concerns with respect to TRIPS are basically limited to three areas:

- granting of product patents to pharmaceuticals and agro-chemicals;
- patenting of micro-organisms or life forms, including patenting of products based on our bio-diversity and traditional knowledge in other parts of the world; and
- establishing an effective *sui-generis* system for the protection of new plant varieties, i.e. plant breeders' rights, which recognises and rewards the traditional contribution of rural communities to the conservation of bio-diversity.

Our response to the TRIPS Agreement would therefore need to focus on these specific issues of concern and work out possible ways and means to deal with them within the ambit of the TRIPS Agreement.

In view of the importance that the protection of IPR has now come to occupy in international trade, economic and scientific cooperation relations, it is in our best interest to gain acceptance in a world that recognises and respects IPRs. Our approach need not be based on the assumption that there is an inherent or irreconcilable conflict between the protection of IPR and the protection of our genuine public interest concerns. Rather, our

approach should be to analyse each form of IPR on its individual merits, especially the nature and magnitude of the public interest involved, and determine the legal and institutional framework needed to maximise the benefits and minimise the potential adverse effects.

The real implications of Articles 70.8 and 70.9 of the TRIPS Agreement do not lie in the granting of Exclusive Marketing Rights (EMR), but in the fact that the product patent system for pharmaceutical and agro-chemical products takes effect from January 1, 1995. This means that Indian companies will not have the freedom that they had enjoyed under the Indian Patents Act, 1970, to reverse/engineer new patented pharmaceutical products that come into the world market some time after the year 2003 on the basis of product patent applications filed in India and elsewhere on or after January 1, 1995.

The past 15 years (from 1983 to 1998) have seen the introduction of about 650 new patented drugs in the world market. Of these, 72 have been introduced into the Indian market under our existing dispensation between 1986 and 1998. In the last five years, i.e. 1994 to 1998 alone, 39 new drugs have been introduced in the Indian market.

There has generally been a gap of three to five years, if not more, between the introduction of a new patented drug in the world market and its subsequent introduction in the Indian market. It can therefore be surmised that the Indian market may, on average, see 5 or 6 new patented drug introductions each year in the foreseeable future. Moreover, since it generally takes 8 to 10 years for a new patented drug to come into the world market from the date of

filing a patent application, and since Articles 70.8 and 70.9 of the TRIPS Agreement apply only to those pharmaceutical and agro-chemical products for which product patent applications are filed in India and abroad on or after January 1, 1995, it is most unlikely that any such product will be able to seek an EMR in India earlier than the year 2003. In any event, EMR is a self-extinguishing provision because from January 1, 2005, the product patent system will take effect. There will therefore be extremely few products, probably less than 10, that will seek EMR. Our major attention should therefore be concentrated not on EMR but on how we manage the product patent system in the future and address our public interest concerns.

The paper suggests a two step approach:

(i) to enact the required legislation before mid-April 1999 to comply with the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement in order to get the WTO dispute out of the way; and

(ii) to focus on the comprehensive revisions required in our Patents Act to fulfill all the other requirements of the TRIPS Agreement.

The transition period for this comprehensive revision is due to expire on 31 December 1999. In the second stage, the questions that need to be examined are: is it better to introduce the product patent system straight away rather than going through the EMR route? If so, how can we deal with the issue of product patenting of products other than pharmaceuticals and agro-chemicals, especially patenting of

micro-organisms? Another major issue concerns the compulsory licensing provisions within the ambit of the TRIPS Agreement because the extension of the products patent system and the nature of compulsory licensing provisions are closely interlinked. Such an examination will obviously require extensive debate. It is therefore in the best interest of the nation to uphold the legislation required immediately to fulfill the obligations under Articles 70.8 and 70.9 of the TRIPS Agreement.

## Report of Discussions

The discussions at the seminar proceeded along three broad strands:

(i) concerns over Exclusive Marketing Rights (EMR);

(ii) advantages/disadvantages of switching over to a product patent regime straight away; and

(iii) broader issues of reforming the patent regime.

**Exclusive Marketing Rights**

Mr. A.V. Ganesan's core argument was that since it takes typically 8-10 years for a drug to move from the patent application stage to the market, it is highly unlikely that any new patented drug will seek EMR in India before the year 2003. In fact, it is reasonable to say that **no more than 5 to 10 drugs would at best qualify for EMR in India by December 31, 2004.** Therefore the concern about the magnitude of EMR is misplaced.

The five criteria for granting EMR, as stated in Ganesan's paper are:

(i) an application has to be filed for a patent in any WTO country on or after January 1, 1995;

(ii) a product patent must have been granted in that country;

(iii) the drug should have received marketing approval in that country;

(iv) an application for a product patent should have been filed in India on or after January 1, 1995 under the mail box facility of Article 70.8; and

(v) a marketing approval for the drug must have been obtained from the Drug Controller of India.

Mr. Ganesan pointed out that **EMR is a self-extinguishing provision as it would cease to apply after December 31, 2004 when the product patent system takes over.**

A concern was expressed by one participant that a large number (close to 3,000) of formulations and combinations of known compounds were getting patents and marketing approval in industrialised countries, and that once we open the EMR route all of them would claim EMR in India. Mr.Ganesan responded to this by stating that Articles 70.8 and 70.9 apply only to **new** drugs patented on applications made after January 1, 1995, and that formulations and combinations of **known** drugs were not eligible to receive EMR. He also drew attention to the fact that only about 650 new patented drugs had been introduced in the world market between 1983 and 1998 of which only 72 have so far been introduced in the Indian market. The vast bulk of the 3,000 applications would either not result in commercially marketable products, or if they are based on formulations or combinations of known compounds, they would not qualify to receive either a patent or EMR in India.

In this context, a view was expressed that if the global pharma companies were able to effectively realise their plan of "2000 by 2000", i.e. reducing the interval of "laboratory to market" to 2000 days by the year 2000, then more new patented medicines may enter the market than is assumed in Mr. Ganesan's paper. If this

happens, their effect will be seen in India only after 2003. Their effect on EMR will be insignificant.

Mr. Ganesan drew attention to the fact that **not a single new chemical entity (NCE) has so far come into the world market based on a product patent application filed on or after January 1, 1995.** He also observed that in judging the magnitude of the patent and problems related to EMR, we should not go by the number of patent applications filed. This is because **only a miniscule percentage of the product patent applications ultimately result in marketable products.** In other words, the world sees about 40 new drugs (NCEs) every year, although the product patent applications filed for pharmaceutical products in the world run into several hundred thousands every year. Mr. Ganesan emphasised, and the Drug Controller of India concurred, that the Drug Controller has the authority to follow independent procedures, including field trials, before giving approval to market a patented drug in India. Furthermore, the Patent Office can also reject a patent application if the product does not meet the `novelty' criteria. **This would effectively disallow patenting of drugs already in the "public domain", particularly indigenous medicines.**

The discussion suggested that the EMR provision would neither lead to a flooding of the Indian market by new patented drugs which had not been screened by India, nor that this would be a route for the introduction of known products or products that were already in the public domain in India.

**Product Patent vs. EMR Option**

Many participants expressed the view that India should utilise the full transition period of 10 years available in the TRIPS Agreement and avoid switching over straight away to a full-fledged product patent regime, especially since the magnitude of the EMR problem is likely to be small. Some others believed that since the acceptance of the applications for product patents from January 1, 1995 itself means *de facto* introduction of the product patent system, it would be better if India switched over to the product patent system for pharmaceuticals and agro-chemicals from January 1, 1995 itself and thereby avoid the trap of granting EMR.

Mr. Ganesan observed that at this juncture, it was best to get the dispute in the WTO out of the way by adopting the pending legislation in Parliament, and then focusing on the comprehensive revisions needed in our Patents Act, 1970 to meet the December 31, 1999 deadline of the WTO. During this examination, we would need to decide whether it would be better for us to switch over to the product patent system straight away, and if so, whether it should be limited only to pharmaceuticals and agro-chemicals; or whether the patent system should be extended to other products not eligible for product patents under our existing law; and how issues of patenting of micro-organisms and compulsory licensing can be handled. A comprehensive examination of the issues involved in product patenting would require time. The enactment of the pending legislation in Parliament would not foreclose the decisions that we may take during the examination for revision of our Patents Act, 1970 by December 31, 1999.

Many participants felt that this two step approach would be a viable proposition as it would allow an informed decision to be taken either way after a thorough examination of all the implications.

**Broader Concerns**

The discussions also touched upon the larger issues of whether IPR in general were consistent with public interest in India, and how exactly public interest could be defined in the Indian context. Questions were also raised about the quantitative importance of the patented drugs sector in India and whether this is likely to change in the new IPR regime. Participants felt that the impact of the new regime on the prices of essential products is an issue that needs to be explored.

Summing up the discussion, the Chairperson Dr. R.A. Mashelkar, supported the two step approach. As a scientist involved in the business of generating knowledge, he urged the adoption of a "forward looking" policy that recognised the inventive capacity and genius of Indians and would give a boost to domestic R&D and scientific capabilities. Consistent with the safeguarding of public interest, a wider and a more self-confident vision was needed in addressing the IPR issue to encourage the generation and utilisation of knowledge in the country. Dr. Mashelkar emphasised the urgent need for modernising our Patent Office and strengthening the quality and quantity of human resources needed to examine and process the patent applications.

Dr. Isher Judge Ahluwalia thanked Mr. A.V. Ganesan, Dr. R.A. Mashelkar, the Members of Parliament and other distinguished participants for their active involvement in the discussion of issues and concerns raised in Mr. Ganesan's paper. She assured the gathering that Mr. Ganesan would take count of the comments made at the Seminar and incorporate them in the final version of the paper to be distributed to Members of Parliament during the current session.

**Implications of the Patents (Amendment) Ordinance, 1999***

## 1. Introduction

1.1 The Government of India promulgated the Patents (Amendment) Ordinance, 1999 on January 8, 1999 with a view to fulfilling India's obligations under Articles 70.8 and 70.9 of the "Agreement on Trade - Related Aspects of Intellectual Property Rights" (popularly known as the TRIPS Agreement) of the World Trade Organization (WTO). The Ordinance shall be deemed to have come into force on January 1, 1995, the date from which the WTO became operational and the TRIPS Agreement as a whole came into force. An identical Patents (Amendment) Bill was passed by the Rajya Sabha in its last session in 1998, and the Bill is pending consideration in the Lok Sabha.

1.2 This discussion paper seeks to analyse in simple terms, the implications of Sections 70.8 and 70.9 of the TRIPS Agreement and to suggest possible ways of dealing with the subject matter. More specifically, the paper attempts to address the following :

- requirements of Articles 70.8 and 70.9[1]
- background to the incorporation of Articles 70.8 and 70.9
- implications of Articles 70.8 and 70.9, including the likely nature and extent of incidence of "exclusive marketing rights" (EMR)
- pros and cons of introducing product patents straight away rather than granting EMR

- precautions to be taken in accepting product patent applications and granting EMR
- recommendations relating to the Patents (Amendment) Ordinance, 1999.

1.3 Although the purpose of this paper is to analyse the implications of only Articles 70.8 and 70.9 of the TRIPS Agreement, it would be worthwhile to refer to the TRIPS Agreement as a whole so that the larger perspective is also kept in view during the discussion of this paper.

1.4 A fundamental assumption of this paper is that India will fulfill its obligations under the TRIPS Agreement as has been its practice in all international agreements.

## 2. TRIPS Agreement – An Overview

2.1 Stated in simple terms, an intellectual property means a creation of the human mind that is of value to the society, and intellectual property rights (IPR) are rights granted by the State to persons for creations of their mind. The TRIPS Agreement of the WTO covers nine categories of intellectual property, namely, copyright and related rights, trademarks including service marks, geographical indications, industrial designs, lay-out designs of integrated circuits, trade secrets, patents, patenting of micro-organisms, and protection of new plant varieties (i.e. seeds and other propagating material)[2]. The TRIPS Agreement lays down the minimum levels of substantive norms and standards to be followed by member countries for the protection of these intellectual property rights as well as for their enforcement.

2.2 The debate in our country over the TRIPS Agreement is overwhelmingly focussed on the issue of patents as if it were the only form of IPR covered by the TRIPS Agreement. It is worth remembering in this context that in respect of the first six categories of IPR (para 2.1 above), our existing laws, regulations and procedures or the laws and regulations we are prepared to undertake on the basis of our own judgment are largely in consonance with the requirements of the TRIPS Agreement. Even if some changes are needed in some of our existing laws, they are of a minimal nature. For example, the TRIPS Agreement requires computer software to be protected as a copyright. Our Copyright Act was amended as far back as 1983 to include the protection of computer software as a copyright. The TRIPS Agreement requires that lay-out designs of integrated circuits should be protected in accordance with the provisions of the "Treaty on Intellectual Property in respect of Integrated Circuits" (the IPIC Treaty) which was adopted in Washington in May, 1989.[3] India is a signatory to this treaty and stands committed to enacting a legislation on this subject.

2.3 With respect to the protection of geographical indications, it is becoming increasingly clear that it is in our own interest to enact legislation to protect our products like Basmati Rice or Darjeeling Tea in the same manner as Scotch Whisky and French Champagne are protected by the geographic appellation laws of the countries that produce them.

2.4 Our track record in enforcing IPR in the areas of copyright, trademarks, industrial designs and trade secrets has been very good. The judicial pronouncements of our courts have safeguarded the legitimate interests of the owners of IPRs on a par with the best legal traditions of the world.[4] India does not belong to the league of countries accused of indulging in systematic or large scale piracy of IPRs in products such as films, musical recordings, books, computer software and data bases. On the contrary, we have a large stake in protecting our IPR adequately in these areas.

2.5 It is therefore in our best interest to generate the impression that India believes that IPR need to be recognised and respected and the legal and judicial framework to provide and enforce IPR needs to be put in place. Rather, our basic approach should be to examine each form and issue of IPR on its individual merits, analyse the implications, especially the nature and magnitude of the public interest involved, and determine the legal and institutional framework suitable to maximise the benefits and minimise potential adverse effects.[5]

2.6 Such an approach would reveal that although the TRIPS Agreement establishes minimum standards for the protection of nine forms of intellectual property, our concerns are basically limited to

- patenting, and that too in respect of granting **product patents** to pharmaceuticals and agro-chemicals;
- patenting of micro-organisms, and that too in respect of

(a) patenting of naturally occurring genetic material,

(b) patenting of products based on our bio-diversity and traditional knowledge in other parts of the world; and

- establishing an effective **sui generis** system for the protection of new plant varieties, which recognises and rewards the traditional contribution of rural communities to the conservation of bio-diversity.[6]

2.7 Our response to the TRIPS Agreement would, therefore, need to focus on the specific issues of concern in these three areas and to work out possible ways and means to deal with them. In doing so, it is important to segregate the IPR and non- IPR issues. While IPR issues must necessarily be handled within the framework of the TRIPS Agreement, we are free to address the non-IPR issues by establishing appropriate legal, regulatory, and institutional frameworks to take care of our concerns. With respect to IPR issues also, there is scope for dealing with our public interest concerns within the ambit of the TRIPS Agreement.

2.8 However, until we have had some experience of implementing the new IPR regime, it is advisable for us to proceed on the assumption that there is an irreconcilable conflict between our public interest needs and the obligations entailed by the TRIPS Agreement.[7] Since the TRIPS Agreement is a multilateral agreement, it will also be useful to look at

how other countries, particularly other developing countries, have dealt with the same issues.

2.9 In the overall context, we should not lose sight of the fact that the protection and enforcement of IPR has now become a major and inevitable component of international economic, trade and scientific cooperation relations. The main reasons for this development are that technology is increasingly becoming the driving force behind international competitiveness and that technology itself, is increasingly becoming a valuable business, commercial and tradeable asset. Secondly, there is a virtual explosion in new technologies in which industrial countries are establishing a huge lead over developing countries. Thirdly, the costs of Research and Development (R&D) are rising sharply, the more so due to growing health, safety and environmental standards.[8] Fourthly, the ability of countries, especially developing countries, to copy or make use of the products and technology created by others is also increasing, giving rise to a clamour for "pirated products" in areas such as pharmaceuticals, chemicals, computer software, films, compact discs, audio and video products and branded consumer articles. Lastly, large transnational corporations (TNCs) are now the major generators, and if not the generators, financiers, purchasers and users of new and R&D intensive technologies. Thus, the protection of technologies, i.e. protection and enforcement of IPR, is increasingly becoming a key factor for accessing, penetrating, protecting and dominating markets around the world, especially for TNCs in industrialised countries.

2.10 Technology or investment agreements between business enterprises, even technology cooperation or collaboration agreements between research/academic institutions, between research/academic institutions and business enterprises, and even between governments are unlikely to be concluded in the future unless the agreement addresses the issue of IPR. Our wisdom and ingenuity should therefore be directed towards establishing an IPR system based on internationally accepted norms and standards (as inscribed in the TRIPS Agreement as well as in numerous international conventions on IPR administered by the World Intellectual Property Organization), which would give a fillip to the full utilisation of our own scientific and technological talents. It would encourage the recognition of India as an attractive destination for investment and collaboration in leading-edge technologies, and at the same time take care of our genuine public interest concerns.

## 3. Requirements of Articles 70.8 and 70.9

3.1 Article 65.2 of the TRIPS Agreement allows developing countries a transition period of five years, with effect from January 1, 1995, to implement the provisions of the TRIPS Agreement as a whole. But Article 65.4 of the Agreement provides for an exception to this general transition period. According to Article 65.4, if a developing country has not permitted product patents to any class of products under its law as on January 1, 1995, it can take another five years to amend its law to provide product patents to those classes of products. In other words, the transition period to extend product patents to those classes of products will last up to December 31, 2004.

3.2 The Indian Patents Act, 1970 (which came into force on April 20, 1972) does not prohibit product patents *per se*. Product patents are permissible under our existing law for all manufactured articles and substances excepting the following:

(i) food, as defined in the Act,

(ii) medicine or drug, as defined in the Act, which includes not only **pharmaceutical products** and their intermediates, but also **agro-chemicals**, like pesticides, insecticides, germicides, weedicides, fungicides, etc.,

(iii) chemicals, i.e. any product produced by a chemical process, which also includes alloys, optical glass, semi-conductors and inter-metallic compounds. Fertilisers, for example, will fall under our law in the category of "chemicals" and not under the definition of "medicine or drug" mentioned in (ii) above,

(iv) living things, which include **micro-organisms and seeds.**

In terms of Article 65.4 of the TRIPS Agreement, India has a transition period of ten years up to December 31, 2004 to amend its law to extend product patents to these four classes of products.

3.3 It may be worth explaining here that a patent is given for an **"invention**" (i.e. something created or innovated by the human mind) and not for a **"discovery**" (i.e.

something that has pre-existed and has only been discovered). The invention covered by a patent may be a "product" or a "process" or both. To be eligible to be given a patent, the invention must satisfy three basic criteria:

First, it must be **"new"** or **"novel";** that is to say, it must not have been known, used, sold or published anywhere in the world prior to the date of filing the patent application. In legal parlance, it must not have already been in or it must not have entered the "public domain".

Second, the invention must involve an **"inventive step**". In essence, this means that it should involve a significant advancement over the existing state of technology in that field. In legal parlance, it should be "non-obvious" to someone well versed in that field of technology.

Third, it should be "**useful"** in industry or agriculture, that is to say, it should have a practical applicability in industry or agriculture.

The TRIPS Agreement does not alter these fundamental criteria for grant of patents. What it requires is that patents, both for products and processes, must be given in all fields of technology without exception. The popular apprehension in our country that existing things, i.e. things already known and used by us, will get patented and will come under the monopoly of the patent's owners elsewhere in the world is therefore not well founded.

Patents can be given only for new inventions when those inventions involve a substantial technical advancement over what is already known on the subject.

3.4 It is also worth mentioning here that technology can be broadly divided into two categories**: "know-how"** and **"patents**". A patent is given only if the applicant gives a full and complete disclosure of his/her invention so that any person reasonably skilled in the art is able to operate or repeat the invention. The grant of a patent (i.e. giving exclusive rights to the inventor for a limited period for making, using and selling the invention) is often regarded as a quid pro quo for the inventor making a full disclosure of his/her invention rather than keeping it as a secret. On the other hand, an inventor is open to the option of keeping his/her technology or "know-how" secret, if he/she is confident that he/she can maintain secrecy or enforce "confidentiality obligations" on persons to whom he/she discloses his/her technology (including those to whom he/she licenses his/her technology). It is a normal business practice to keep "know-how" a secret, where it is feasible for the owner to keep it as a secret. That is why it is often stated that the value of a know-how lies in its secrecy, while the value of a patent lies in its disclosure. In India, we protect the secrecy of know-how (i.e. trade secrets) under various laws as strongly as possible and on a par with the best in the world. But we have reservations over the degree of protection to be provided under the patent route. The pharmaceutical or agro-chemical industry does not have the option of the 'know-how" or secrecy route because the products and processes have to be fully disclosed to the regulatory authorities before they can be marketed to the public. This is one of the major reasons why the availability of product patents is a matter of importance to these industries.

3.5 Coming to Articles 70.8 and 70.9 of the TRIPS Agreement, these articles place a limitation on the transition periods allowed under Articles 65.2 and 65.4 of the Agreement in respect to two classes of products only, namely, pharmaceuticals and agro-chemicals. Articles 70.8 and 70.9 come into play if a country has not provided for product patents to pharmaceuticals and agro-chemicals as on January 1, 1995. Article 70.8 establishes what is more popularly known as the **"mail-box"** mechanism, while Article 70.9 provides for **"exclusive marketing rights (EMR)"** to the applicants under certain conditions.

3.6 Article 70.8 requires that applications for product patents for pharmaceuticals and agro-chemicals must be accepted from January 1, 1995. These applications shall be kept pending (in a "mail-box") till the country's law is amended in respect of giving product patents for pharmaceuticals and agro-chemicals, the last possible date for giving effect to such an amendment being January 1, 2005 as noted earlier. As and when the law is amended, the pending applications shall be examined, and if the criteria for patentability are met, a product patent shall be granted. The duration of the patent shall be the **remainder** of 20 years counting from the date of filing of the application.

3.7 To give an example, suppose a product patent application is filed in the United States on January 1, 1995 and it is filed in India on or before December 31, 1995 (i.e. within 12 months of the first filing in another member country of the WTO).[9] The patent application shall be given a "priority date" of January 1, 1995 and kept pending in our country. Suppose our Patent law is amended and the amendment is effective from January

1, 2005 then, if the pending application is accepted and a product patent is granted, the duration of the patent in India shall be 10 years - from January 1, 2005 to December 31, 2014. In the United States, the duration of the product patent will be 20 years from January 1, 1995 to December 31, 2014. In this example, suppose our law is amended with effect from January 1, 2000. The term of the patent in India shall be 15 years - from January 1, 2000 to December 31, 2014. The term of the patent for an accepted application shall be calculated in this manner although it may take some time after the law is amended for the pending patent application to be examined and accepted or rejected.[10]

3.8 Article 70.9 envisages a situation where the product patent application pending in the "mail-box" under Article 70.8 has been granted both a product patent and a marketing approval in another member country that follows the product patent system. The Article lays down that if the following conditions are satisfied, namely,

- a product patent application has been filed in another member country on or after January 1, 1995;
- a product patent has been granted in that country on that application;
- a marketing approval has also been granted for that product in that country;
- a product patent application has been filed in the "mail box" country on or after January 1, 1995 under Article 70.8 and it is pending; and
- an application is made in the mail box country for exclusive marketing rights,

then "exclusive marketing rights" (EMR) for the product shall be granted by the mail box country to the applicant for a period of five years **after the applicant has obtained marketing approval in the mail box country** or until the pending application for product patent is accepted or rejected by the mail box country, whichever period is shorter. (If a product patent is granted, the patent itself will confer exclusive marketing rights and so there will be no break in the applicant enjoying the exclusive marketing rights. If the application for a product patent is rejected, then the EMR shall cease with effect from the date of rejection).

3.9 It needs to be noted that the applicant must seek "marketing approval" in the mail box country also. The authority to whom an application is to be made for a marketing approval, and the procedures for grant of a marketing approval for a pharmaceutical or agricultural product, are different from and independent of the authority for receiving and granting a patent (i.e. the Patents Office). Those procedures are not curtailed by the TRIPS Agreement. The rationale behind the provision for grant of EMR is that a product patent application is pending and a transition period up to 10 years is available to the mail box country to amend its law to grant product patents.

3.10 Thus, the sum and substance of Articles 70.8 and 70.9 of the TRIPS Agreement is that India should receive product patent applications for pharmaceuticals and agro-chemicals from January 1, 1995 itself and that exclusive marketing rights should be granted to an applicant if he/she applies for those rights and if the conditions specified in Article 70.9 are satisfied.

## 4. Background to Articles 70.8 and 70.9

4.1 The industrial countries, led by the USA and some European countries, were keen that notwithstanding the transition period allowed to introduce the product patent system, pharmaceutical and agro-chemical products should be granted **"pipe line"** protection during the transition period. Pipe line protection means that if a product (i.e. a pharmaceutical or agro-chemical product) has been granted a product patent in an industrialised country, then it must be granted an exclusive marketing right in a developing country as well even though the developing country may not have a product patent system for that product.

4.2 The United States pressed for such pipe line protection to be given for all pharmaceutical and chemical products that had been granted product patents in the USA on or after January 1, 1986. (The Uruguay Round Multilateral Trade Negotiations were launched in September 1986.) At the minimum, the demand of the USA was for pipe line protection to be given to products that had been granted patents in industrialised countries in the years before the TRIPS Agreement came into force (as for example, product patents given on or after January 1, 1990). Although some of the European countries were also equally keen for some form of pipe line protection, they were flexible as to the date from which such protection was to be given effect. The cost of R&D and the lead time required to bring a pharmaceutical product into the market from the patent stage were stated to be the reasons behind the demand for pipe line protection. This demand for pipe line

protection under the TRIPS Agreement gathered force because the United States was also pursuing it in its bilateral negotiations with some countries and was able to secure it. To cite an example, following many months of bilateral negotiations between the USA and China over some serious trade disputes, China agreed in January 1992 to provide pipe line protection to pharmaceutical and other chemical products patented in the USA since January 1, 1986, although China had earlier insisted that such pipe line protection could cover only future inventions.[11]

4.3 On their part, the developing countries, including in particular India, argued against any form of pipe line protection. They wanted the transition period to be clean without any limitations or encumbrances. Moreover, they wanted that the transition period for introducing product patents in all fields of technology should be longer, at least ten years if not more. The industrialised countries counter argued that if there were a clean transition period of ten years, the first new drug to enjoy product patent rights in a developing country market would be after 18 to 20 years from the date when the TRIPS Agreement came into force, since it takes at least eight to ten years for a drug to be brought into the market from the date of filing a patent application.

4.4 It was also pointed out by the developing countries, including in particular India, that patents are national in jurisdiction and that it would be illegal to grant exclusive marketing rights on the basis of patents granted elsewhere. There ought to be a legally tenable nexus for the grant of exclusive marketing rights failing which courts could strike down the grant of such rights.

4.5 The negotiations finally resulted in what is known as the Swiss version of pipe line protection, which is incorporated in Article 70.8 and 70.9 of the TRIPS Agreement. It rules out any form of pipe line protection to pharmaceutical or agricultural chemical products that have been granted product patents elsewhere prior to January 1, 1995 and also to products that might get patents elsewhere after January 1, 1995 on the basis of patent applications filed prior to January 1, 1995. This is because Article 70.9 applies only to those pharmaceutical and agro-chemical products for which product patent applications have been filed elsewhere, as well as in the "mail-box" country, on or after January 1, 1995. At the same time, it requires applications for product patents for pharmaceutical and agro-chemical products to be accepted by the "mail-box" countries from January 1, 1995 itself, which means that there is no clean transition period available to them so far as these two products are concerned. The acceptance of such applications, and their being kept pending for examination during the transition period, is supposed to provide a nexus between the acceptance of the application for product patent rights and the granting of exclusive marketing rights during the transition period.

4.6 Regardless of how the legality of the grant of EMR is settled by courts in case any dispute arises, Article 70.8 ensures product patent protection for pharmaceutical and agro-chemical products for which product patent applications are filed on or after the coming into force of the TRIPS Agreement, i.e. January 1, 1995.

## 5. Implications of Articles 70.8 and 70.9

5.1 The debate in our country has overwhelmingly been concentrated on the implications of the grant of exclusive marketing rights (EMR) under Article 70.9. Article 70.9 is perhaps the only article of the TRIPS Agreement which is self- extinguishing in nature. It will expire automatically on December 31, 2004 in any case or even earlier if a country chooses to introduce the product patent system for pharmaceuticals and agro-chemicals without availing of the full transition period of ten years from January 1, 1995. The impact of EMR will therefore have to be judged by the fact that the EMR itself will expire by December 31, 2004 at the latest and that in any case the product patent system will take over from January 1, 2005. (A product patent confers on its holder much more than exclusive marketing rights).

5.2 In order to assess the magnitude of the likely incidence of EMR upto December 31, 2004, it is necessary to look at both the number of new patented drugs (or agro-chemicals) coming into the Indian market and the time it usually takes for a new drug to come into the world/Indian market from the date a product patent application has been filed for it. An analysis for the ten calendar year period 1983 to 1992 shows that the total number of new drugs introduced into the **world market** in this period was 433. It is perhaps worth mentioning here that every patent does not result in a commercial product. According to the international pharmaceutical industry, if about 5,000 compounds enter pre-clinical testing, only one gets finally approved for commercial marketing. Thus, the 433 new drugs that the world saw in the period 1983 to 1992 would have been picked out of several

lakhs of product patents taken over ten or more years. In other words, the vast bulk of drug patents fall by the wayside and do not see the commercial market.

5.3 Be this as it may, what is relevant for this discussion is that out of the 433 new drugs the world saw during the period 1983 to 1992, the number introduced into the **Indian market** till 1993 was only 33. The time lag between their introduction into the world market and the Indian market was, generally speaking, three to five years. Moreover, of the 33 drugs, nine had been introduced only by the patent owners themselves, five by both the patent owner and Indian companies, and the remaining 19 by Indian companies only. Again, out of the 33 drugs introduced into the Indian market, only four or five could be regarded as top selling drugs, i.e. drugs with an annual turnover in excess of a few crores of rupees.

5.4 If we look at the data of the last five years, i.e. the five calendar years 1994 to 1998, the Indian market saw the introduction of 39 new patented drugs. Most of these new drugs, about 30 in number, had been introduced into the world market between 1983 and 1992. The gap between their introduction into the world market and the Indian market has been five or more years in many cases. The details of these drugs are given in Annex 1.

5.5 These data show that the world sees about 40 new drug introductions every year (on an average) and India sees perhaps a tenth of these each year. Even allowing for a sharp increase in the number of new drugs that might be introduced into the Indian market,

it is reasonable to assume that India may at best see five to six new patented drugs each year (on an average) in the foreseeable future.

5.6. As noted earlier, some of the new drugs (about a quarter of the total) get introduced by the patent owner only, either by way of local production or by way of imports. In other words, the introduction and marketing of some of these new drugs are carried out by the patent owner only even under the existing dispensation.

5.7 Let us now consider the time taken for a new drug to get introduced into the world market from the date of filing of a patent application. According to the Pharmaceutical Manufacturers Association (PMA) of America, it takes on an average 12 years for an experimental drug to travel from the laboratory to the commercial market: 3.5 years for pre-clinical testing, 6 years for clinical trials, and 2.5 years for Federal Drug Administration (FDA) approval.[12] Allowing for some over estimation in this statement, and taking into account the actual period taken by most new drugs to enter the world market since the laboratory stage, it is reasonable to say that a new drug takes, on an average, about eight to ten years to enter the world market from the date of filing a patent application. In most cases the introduction in the Indian market will be later than the introduction in the world market by at least a few years. (As noted in paras 5.3 and 5.4 above, in the case of the 72 new patented drugs introduced in the Indian market in the last about 12 years, the gap was generally three to five years, if not more. Since EMR is sought by the patent owners themselves, the gap between world and Indian introductions may possibly get reduced).

5.8 Articles 70.8 and 70.9 of the TRIPS Agreement apply only to patent applications filed on or after January 1, 1995. Assuming a minimum of eight years for a new pharmaceutical product to enter the Indian market from the date of filing of a patent application, the EMR picture will look as follows:

| Year of patent application for the product | Earliest likely year for EMR taking effect in India |
|---|---|
| 1995 | 2003 |
| 1996 | 2004 |

5.9 The reason why the table is not continued beyond 1996 is that the products arising out of patents applications filed in the year 1997 or later are most unlikely to come into the Indian market earlier than the year 2005 and that in any event the product patent system would come into effect from January 1, 2005. There is no need for EMR once the product patent system takes effect.

5.10 Considering that the number of actual new drug introductions into the Indian market will at best be five or six drugs per year and that some, if not many, drugs may take more than eight years (from the date of patent application) to come into the world or Indian market, it is evident that the number of new drugs which will seek EMR will be extremely few, most probably less than ten. Further more, the question of EMR is relevant - that is the question of the patent owner alone having the right to market the product and others

being prohibited from doing so - only if there are alternate producers who are able and ready to introduce the same product in the market. Once product patent applications are accepted from January 1, 1995 and kept pending as per the TRIPS Agreement, it is hard to visualise Indian companies making investment in R&D and production facilities and trying to produce that product knowing well that the product patent system is due to take effect in India from January 1, 2005 at the latest.

5.11 Although the above analysis is focussed on pharmaceuticals, it can be said that the same situation prevails more or less for agro-chemicals as well.

5.12 Our concern and concentration over the issue of exclusive marketing rights is therefore exaggerated, if not misplaced. There will only be few products which will seek or qualify for EMR in terms of the provisions of Article 70.9, which as stated earlier is self - extinguishing once the product patent system takes effect no later than January 1, 2005. **The real implication of the TRIPS Agreement lies not in the EMR provisions, but in the fact that product patent applications for pharmaceutical and agro-chemical products have to be accepted from January 1, 1995 itself.** In other words, the real implication is that the product patent system for these two products comes into effect *de facto* from January 1, 1995 itself without any transition period. As noted earlier, the main reason behind industrialised countries not agreeing to a clean transition period of five or ten years is that it takes eight to ten years, if not more, for a drug to be marketed from the date of filing a patent application, and that therefore the product patent system should take effect from at least the date of entry into force of the TRIPS Agreement

even if the situation prior to that date is ignored. The EMR provisions were intended only as a stop-gap arrangement pending the amendment of national laws to provide product patents for pharmaceuticals and agro-chemicals.

5.13 Thus, the real significance of Articles 70.8 and 70.9 is that in respect of pharmaceutical and agro-chemical products for which product patent applications were filed on or after January 1, 1995, Indian companies will not have the freedom that they had enjoyed under the Indian Patents Act, 1970 to produce and market those products in India or elsewhere without any legal restrictions. The impact of this crucial and significant change will be felt in the case of new drugs that will come into the market after 2003, more probably after 2005. At the same time, we need to keep in view the fact that the product patent system, including in the area of pharmaceuticals and chemicals, has now become an accepted norm even in most developing countries. Our energies would therefore need to be focussed on how we manage a product patent system and use it for our own technological and economic progress, while at the same time safeguarding our genuine public interest concerns.[13]

5.14 It may be useful to look at how some other developing countries have handled this subject. The Dunkel Draft of the WTO Agreements, including the TRIPS Agreement, had come into existence in December 1991, although the Uruguay Round negotiations were formally concluded in December, 1993 and the results of the negotiations were ratified in Marrakesh in April 1994. The basic provisions of the TRIPS Agreement were thus known in December 1991 itself.

5.15 Thailand amended its Patents Act in April 1992 to provide *inter-alia*, for product patents in food, pharmaceutical and chemical sectors and to raise the duration of the patents to 20 years.

5.16 The first comprehensive Patent Law of China was enacted in March, 1984 and had come into force on April 1, 1985. That law did not provide for product patents in the food, pharmaceutical and chemical sectors. Although China is not yet a member of the WTO, following its afore mentioned bilateral negotiations with the United States in January, 1992, it amended its patent law in September, 1992 to (a) provide for product patents in food, pharmaceutical and chemical sectors as well as for micro-organisms; (b) raise the duration of patents from 15 to 20 years; and (c) revise the provisions of compulsory licensing to bring them in conformity with the TRIPS Agreement. As a result, the amended Chinese Patent Law is in consonance with the requirements of the TRIPS Agreement. In addition, China promulgated an ordinance in December 1992 on the protection of foreign drug patents in order to give pipe line protection to drugs covered by foreign patents since January 1, 1986 that had not yet been marketed in China.

5.17 The Latin American developing countries, which were the earliest developing countries to exclude food, pharmaceutical and chemical sectors from patent protection, have over a period of time switched over to the product patent system in all sectors, and by the time the Uruguay Round negotiations had concluded, had introduced product patents in the food, pharmaceutical and chemical sectors. The ASEAN countries, including

Thailand (being the last), have adopted the product patent system. For the vast majority of developing countries, therefore, Articles 70.8 and 70.9 do not come into play because their laws provided product patents for pharmaceuticals and agro-chemicals even before January 1, 1995.

## 6. Pros and Cons of Introducing Product Patents Straight Away

6.1 There has been a suggestion that since the granting of EMR may be more injurious to Indian interests than granting a product patent, it would be better to introduce the product patent system straight away for pharmaceuticals and agro-chemicals, i.e. from January 1, 1995 itself. There is some merit in the suggestion for the introduction of a product patent system straight away, but not for the reason that the EMR concept is more injurious than granting a product patent. The rationale for introducing the product patent system straight away should lie in the fact that the acceptance of product patent applications for pharmaceuticals and agro-chemicals from January 1, 1995 itself means really the *de facto* introduction of the product patent system for these two products from that date. The subsequent steps like amending the law to allow product patents and granting of an EMR if an application for EMR is made, are merely procedural requirements to take care of the transition period. The priority date for granting patent rights will in any case count from the date of filing the application, and the duration of 20 years will also count from that priority date. As explained earlier, the EMR is not the key or real issue because there will be extremely few products which may qualify for EMR, that applications for grant of EMR are unlikely to arise earlier than the year 2003, and that

in any event the product patent system will take over by January 1, 2005 at the latest. We will be missing the wood for the trees if we overly concentrate our attention on the EMR issue in abstract without regard to the likely magnitude of the EMR problem and its self - extinguishing nature.

6.2 Leaving aside the magnitude of the EMR problem, the question still remains whether it is better to go in for the product patent system straight away as we are required to accept product patent applications from January 1, 1995 and grant product patent protection on that basis. As noted earlier, Thailand and China preferred this option and amended their laws in 1992 itself to allow product patents in the food, pharmaceutical and chemical sectors. (China also allowed patenting of micro-organisms.) The Latin American countries also followed this route. Since they had amended their laws in this manner prior to the coming into force of the TRIPS Agreement (i.e. January, 1, 1995), they do not come within the purview of Articles 70.8 and 70.9. This does not mean that they do not give exclusive marketing rights to patent owners. The product patent rights would automatically include EMR and all the other rights associated with a product patent.

6.3 In our present situation, we need to consider three aspects: (i) the time limit, i.e. April 1999, by which we need to amend our law to comply with the WTO Appellate Panel ruling in the dispute over our non-compliance with Articles 70.8 and 70.9; (ii) the products which are not currently eligible for product patents under our Patents Act, 1970; and (iii) the transition periods available to us to comply with various provisions of the TRIPS Agreement in the area of patents.

6.4 Apart from pharmaceuticals and agro-chemicals, the following products are not eligible for product patents under our existing law: food items, intermediates used for the manufacture of medicines and drugs, chemicals, alloys, optical glass, semi-conductors, inter-metallic compounds and all living things, including micro-organisms. In respect of all these products, including micro-organisms, the TRIPS Agreement allows us a transition period of ten years, i.e. up to December 31, 2004 to introduce product patents. It is only for pharmaceutical and agro-chemical products that there is no transition period and we have to accept product patent applications from January 1, 1995 itself. If we wish to introduce the product patent system straight away for these two classes of products, a question for consideration is whether we need to extend the product patent system straight away to all these other products, especially micro-organisms, as well. It would not make much sense to introduce the product patent system in a piecemeal manner for different classes of products.

6.5 The general transition period allowed under the TRIPS Agreement is five years ending on December 31, 1999 for complying with all the provisions of the agreement other than the introduction of the product patent system. Our Patents Act, 1970 will require a comprehensive revision in order to meet the stipulations of the TRIPS Agreement, especially with respect to raising the duration of patents to 20 years uniformly for all sectors, abolition of the system of automatic compulsory licensing, revision of the provisions relating to compulsory licensing and non-working of patents, and reversal of burden of proof in the case of process patents. In addition, as we are not contemplating the

protection of new plant varieties (i.e. seeds and other types of propagating material of plants) through patents, we need to have a new legislation for the protection of 'Plant Breeders' Rights'.

6.6 All this legislative work would have to be completed by December 31, 1999 after a thorough examination of the issues involved and a transparent and well-informed debate on the subject. In particular, there has to be a detailed examination of how our genuine public interest concerns can be addressed within the framework of the TRIPS Agreement so far as IPR issues are concerned and by other legislation and regulatory frameworks so far as related non-IPR issues are concerned. This is massive job and is much more important, complicated and critical than the legislation under consideration to comply with the requirements of Articles 70.8 and 70.9. This work needs to be started without any further delay if we are to meet the dead line of December 31, 1999 for complying with the general requirements of the TRIPS Agreement.

6.7 So far as Articles 70.8 and 70.9 are concerned, we are presently under an obligation to enact a legislation to comply with these provisions by mid-April 1999 as a result of the Dispute Settlement Body ruling of the WTO. The merits and demerits of introducing a product patent system straight away cannot be debated and settled before April 1999 if we are to take into consideration all the matters mentioned in paras 6.4 and 6.5.

6.8 It would therefore be prudent for us first to enact a legislation before mid-April 1999 to fulfill the requirements of Article 70.8 and 70.9, namely establishing a system for

filing of product patent applications for pharmaceuticals and agro-chemicals, and a system for grant of EMR if and when applications for EMR are received. Once this legislation is enacted, we have time till December 31, 1999 to revise our Patents Act, 1970 to comply with all the other requirements of the TRIPS Agreement. As noted above, this revision will need to be comprehensive and wide ranging. Rather than considering piecemeal revisions of our Patents Act, during this comprehensive revision process, we can examine also the issue whether it would be better to introduce the product patent system straight away for pharmaceuticals and agro-chemicals; if so, whether it should be confined only to these products or extended also to the other products mentioned in para 6.4; and whether micro-organisms also should be included in such extension.

6.9 In case, we come to the conclusion that it would be better to extend the product patent system straight away for pharmaceuticals and agro-chemicals only or for all products or for all products excluding micro-organisms, the legislation for a comprehensive revision of our Patents Act by December 31, 1999 could incorporate the conclusion reached. That will automatically extinguish the EMR system created under the present immediate legislation. It is therefore not advisable to hold up the legislation immediately required to comply with the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement.

## 7. Precautions for Accepting Product Patent Applications and Granting EMR

7.1 Article 70.8 requires acceptance of product patent applications only and that too only for pharmaceutical and agro-chemical products. Furthermore, Articles 70.8 and 70.9 do not apply to products that have already received patents prior to January 1, 1995 or to products for which patent applications have been filed elsewhere in the world prior to January 1, 1995.

7.2 Therefore, our Patents Office should not accept (or if accepted, reject after a preliminary examination) the following types of applications and prevent their entry into the "mail box":

(i) process patent applications or applications where the claimed invention is not a product;

(ii) product patent applications where the product claimed is not a pharmaceutical or agro-chemical product;

(iii) product patent applications for pharmaceuticals and agro-chemicals where patent applications for the product have been filed elsewhere in the world prior to January 1, 1995. It must be noted that the grace period of 12 months is available only to those patent applications which are filed elsewhere in the world on or after January 1, 1995.

7.3 A process patent application (or even a product patent application) may be accepted otherwise, if it is in accordance with the provisions of the existing Patents Act, 1970. But applications filed in pursuance of the provisions of Article 70.8 and 70.9 of the TRIPS

Agreement should be straight away rejected and not be admitted in the "mail box" if they fall in the above three categories.

7.4 If the above approach is followed, then a patent application like the one involving the so-called "terminator technology" would not be accepted either because it is a process patent application or because the product claimed is not a pharmaceutical or agro-chemical product. A process or product patent application may be otherwise acceptable in terms of our Patents Act, but not for availing of the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement.

7.5 With respect to granting of EMR, two major concerns have been expressed: first, that the required marketing approval may be obtained not in an industrialised country, but in a country where the standards for approval may be lax and lenient; and second, that drugs that were already in existence prior to January 1, 1995 would seek EMR after obtaining 'supplementary' patents or marketing approval in industrialised countries.

7.6 As regards the first concern, the TRIPS Agreement does not impinge on the procedures adopted by the Drug Controller of India for granting market approval. The Drug Controller may require the applicant to carry out adequate clinical trials in India if in his judgment the marketing approval obtained in the other country does not measure up to Indian standards. It must be noted that the Drug Controller grants the "marketing approval" by following his normal procedures unaffected by the TRIPS Agreement, while the Patents Office grants the "exclusive marketing right" as per the provisions of Article

70.9 of the TRIPS Agreement. It is only after obtaining the marketing approval from the Drug Controller that the applicant can apply to the Patents Office for grant of EMR under Article 70.9 of the TRIPS Agreement. The procedures followed by the Drug Controller of India for granting market approval are as stringent as those followed in advanced countries and on an average take about two years for the introduction of a new chemical entity in our market. The Drug Controller does not, and need not have to, grant marketing approval for any new drug automatically on the basis of a marketing approval granted elsewhere in the world. The present procedures followed by the Drug Controller of India are more than adequate to take care of our national interests when approving the introduction of any new drug, whether patented or not, in the Indian market.

7.7 As regards the second concern, Articles 70.8 and 70.9 of the TRIPS Agreement apply only to drugs arising out of patent applications filed on or after January 1, 1995. No pipe line protection is intended for products patented or sold prior to January 1, 1995 anywhere in the world. A practical check for ensuring this is whether the product for which EMR is claimed enjoys a 20 year product patent duration beginning on or after January 1, 1995 in the country of its origin. If it does, then it is obviously a new invention arising after January 1, 1995. Before granting an EMR, our Patents Office should ascertain the patent term of the product in its country of origin. If it is 20 years, the Patents Office should grant EMR subject to other requirements being met, and the product having obtained marketing approval from the Drug Controller. If not, the Patents Office should reject it on the ground that the provisions of Article 70.9 do not apply to the case.

7.8 A concern has been expressed that a large number of new formulations or combinations or new uses of known compounds would seek EMR in India on the basis of patents and marketing approvals obtained in industrialised countries after January 1, 1995. Articles 70.8 and 70.9 of the TRIPS Agreement do not apply to drugs known and used prior to January 1, 1995. As noted earlier, when an application for a product patent for such a product is received under Article 70.8 and the Patents Office finds that the basic patents for the products in question have been taken prior to January 1, 1995, the Patents Office should reject those applications as not being eligible for acceptance under Article 70.8. In addition, when an EMR is sought, the Patents Office should check whether the patent duration for the product is 20 years in the industrialised country from a date beginning on or after January 1, 1995. These kinds of checks on the year of grant and duration of the basic patents of the claimed products would weed out any applications received under Article 70.8 or 70.9 of the Agreement based on products patented, known or used prior to January 1, 1995.

7.9 The precautions mentioned above are in consonance with the TRIPS Agreement and can be incorporated in the implementing regulations. It is a mistaken notion that Articles 70.8 and 70.9 do not allow such examination or checks and that they require passive acceptance of product patents and EMR applications. At the same time, it is a mistake to exaggerate the implications of EMR, which as stated earlier in this paper, may actually come into play only for extremely few products and that too for a limited period ending December 31, 2004 at the latest. Our priority concern and attention should rather

focus on how we can manage the product patent system in the future, and take care of genuine public interest concerns within the ambit of such a system.

## 8. Recommendations

8.1 The Patents (Amendment) Ordinance, 1999 was gazetted on January 8, 1999 and its provisions shall be deemed to have come into force on January 1, 1995. Its objective is to establish the legal framework needed to fulfill the requirements of Articles 70.8 and 70.9 of the TRIPS Agreement, although product patent applications for pharmaceuticals and agro-chemicals are already being accepted by our Patents Office from January 1, 1995 on an administrative basis.

8.2 The Ordinance keeps Section 5 of the existing Patents Act intact and has simply added a new sub-section to say that an application for product patent for a "medicine or drug" (which includes in our law agro-chemicals as well) "may be made" and shall be dealt with in accordance with the provisions incorporated in the Ordinance as new Chapter IV-A under the heading "Exclusive Marketing Rights". Later, when dealing with EMR applications, it says that the application shall be rejected if the product is not an invention within the meaning of the Patents Act, and that if the EMR application is not rejected, the Controller shall grant approval for EMR for a period of five years or till the **grant or rejection of a patent**, whichever is earlier. It would appear that there is a serious legal flaw in keeping the existing Section 5 of the Patents Act, 1970 intact, and thereafter

proceeding with other provisions in the manner contained in the Ordinance. Section 5 of the existing Act prohibits the grant of product patents for pharmaceuticals and agro-chemicals (as also for food and chemicals in general). Unless this prohibition is first removed and the amending legislation permits product patenting of pharmaceuticals and agro-chemicals, the subsequent provisions relating to (a) acceptance of product patent applications, and (b) allowing EMR till the product patent application is accepted for grant of a product patent or rejected for the reason of its not qualifying for grant of a product patent may become inconsistent and illegal.

8.3 It is therefore suggested that in the amending legislation-

(i) the words "or as medicine or drug" be deleted from Section 5(a) of the principal Act;

(ii) the existing Section 5 of the principal Act after removal of the above words be renumbered as sub section (1); and

(iii) a new sub section be inserted as sub section (2) of Section 5 of the principal Act to read as follows:

"In the case of inventions claiming substances intended for use, or capable of being used, as medicine or drug, excepting the substances falling under sub-clause (v) of clause (l) of sub-section (1) of Section 2 of the principal Act, an application for a patent claiming the substance itself may be made and shall be dealt with, without prejudice to the other provisions of the principal Act, in the manner provided in Chapter IV A".

(iv) the existing sub-title to Section 5 be reworded because of the above changes to read "Manner of dealing with inventions relating to specified substances".

8.4 Even if the amending legislation does not include the following matters, the implementing regulations should provide for

(i) rejection of the application for the reasons specified in para 7.2 read with para 7.8 above;

(ii) rejection of the application if the invention claimed is not an invention within the meaning of the principal Act, for which purpose Section 24A (1) of the Ordinance should end at "is not an invention within the meaning of this Act", and the rest of that sentence should be deleted; and

(iii) compliance with the procedures to be followed under Sections 6 to 11 of the principal Act.

8.5 It is not necessary that the rejection of an ineligible application should wait till December 31, 2004 or till an EMR application is made. The examination of an application after December 31 2004 should basically be limited to an examination of the "inventive step" involved, and not for determining the "novelty" criteria. If something has entered the public domain in our country already, the application needs to be rejected on that ground straight away without its being kept pending till December 31, 2004 or till the EMR application is made. Although such cases may be rare, the implementing regulations of the

Act should provide for them. Also, Section 12(1), of the principal Act, quoted in Section 24A(I) of the Ordinance, comes into play only after "complete specifications" have been filed by the applicant for patent. The compliance with the procedures prescribed in the Act under Sections 6 to 11 up to the stage of filing "complete specifications" will therefore need to be spelt out in the implementing regulations.

8.6 The provisions of the Ordinance relating to compulsory licensing, which are contained in Sections 24C and 24D of the Ordinance, require serious rethinking. Firstly, as noted earlier, there will be extremely few products which will qualify for EMR. Secondly, EMR is unlikely to occur for any product, barring if at all exceptional cases, earlier than the year 2003. Thirdly, in any case, the product patent system is to be brought into force with effect from January 1, 2005 at the latest. Once that occurs, the compulsory licensing provisions applicable to patents according to the TRIPS Agreement would take over. Fourthly, as per the provisions of the Paris Convention and the TRIPS Agreement to both of which we are a signatory, no compulsory licence can be given for a period of three years from the date of grant of a patent (which in this case would mean the date of grant of the EMR). This is so even under our existing Patents Act. For reasons not clear, Section 24C(b) of the Ordinance reduces this period to two years. Whether the grace period is three or two years, it will cross January 1, 2005 by which date the product patent system would in any case take over. Lastly, the possibility of grant of a compulsory licence in the case of an EMR rests upon an Indian company having the technology and production facility ready to manufacture the EMR product and wanting to market it.

8.7 As noted earlier, it is most unlikely that any Indian company will make such investment in R&D and production facility in respect of any product for which it knows a product patent application is pending and the commercial prospects of which would get established only when the product is introduced in the world market in all likelihood after the year 2003. The possibility of any Indian company wanting or being in a position to apply for a compulsory licence during the EMR phase ending on December 31, 2004 can therefore be virtually ruled out. This being the nature and magnitude of the EMR problem, there is no point in incorporating compulsory licensing provisions in the Ordinance. Section 24C of the Ordinance will remain a dead section from the practical point of view. Similarly, Section 24D, which also will in all probability be a dead provision, can be justified if it is applicable only in the case of "public non commercial use". (Otherwise, it contradicts or is no different from Section 24C.)

8.8 Sections 24C and 24D run the risk of being challenged in the WTO as being inconsistent with the provisions of Section 70.9 and the TRIPS Agreement. Since in reality there can be or there will be no case of a compulsory licence being granted in respect of an EMR product, it is not necessary or advisable to have Sections 24C and Section 24D in the legislation. At best, if Section 24D is to be retained, the words "for public non-commercial use" may have to be inserted appropriately in its sub-section (1). So far as the issue of compulsory licensing is concerned, what is required is to deal with it under the patent system in the amendments we are required to bring about in our Patents Act by December 31, 1999 ( see para 6.5 above).

8.9 The Ordinance also needs tighter scrutiny and editing. For example, the word "article" should be dropped throughout the Ordinance and only the word "substance" should be used because the Ordinance applies only to what is defined as "medicine or drug" in section 2(1)(l) read with section 2(j)(iii) of the Patents Act. According to these sections, medicine or drug are "substances produced by manufacture". Similarly, the "Explanation" under Section 24A needs careful thinking and drafting. Is it meant to cover both (i) all drugs based on the system of Indian Medicine, and (ii) all substances that are already in the public domain; or is it meant to cover only those drugs based on the system of Indian Medicine that have already passed into the public domain. The latter does not pose a problem because any substance that is already in the public domain cannot be eligible for obtaining a patent. But if all "new" inventions of substances based on the Indian Medicine system are prohibited for EMR (which means they are prohibited also for patenting), then it could affect our own interests in the future.

8.10 Finally, in view of the serious time constraints and in view of the fact that the real problem of concern is not the EMR problem, but the introduction of product patent system for pharmaceuticals and agro-chemicals with effect from January 1, 1995, it would be advisable to enact this legislation immediately to get the WTO dispute on this subject out of the way. At the same time, we should concentrate our energies on the amendments to be brought about in the Patents Act, 1970 by December 31, 1999 to comply with all the other requirements of the TRIPS Agreement. During this examination, we could also resolve the issue whether it would be better to introduce the product patent system straight away from January 1, 1995 for pharmaceutical and agro-chemicals, and if so, whether we

should handle the introduction of a product patent system for other products. Our strategy on the issue of compulsory licensing also could be settled during this examination. The time left is short and the issues to be examined are far more crucial than the legislation under consideration. We therefore need to act swiftly.

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**ENDNOTES**

[1] For the sake of ready reference, the text of these Articles, as well as the text of Article 65 of the TRIPS Agreement relating to `Transitional Arrangements', are reproduced in Annex 2.

[2] The TRIPS Agreement includes patents, patenting of micro-organisms, and protection of plant varieties under one category, but for our discussion, it will be appropriate if they are regarded as three distinct categories.

[3] In addition to the IPIC Treaty, the TRIPS Agreement requires certain additional provisions to be followed in this regard.

[4] It is worth mentioning here that intellectual property rights are private rights. The responsibility of the State is confined to providing the legal, administrative and judicial framework for obtaining the rights and for getting them enforced. In case of any alleged infringement of those rights, it is for the owner of the rights to take recourse to the judicial process to protect his/her rights.

[5] Such a legal framework would need to go beyond the laws pertaining to IPRs *per se***,** such as for example, anti-competition law, consumer protection law, drug marketing law, drug pricing regulations, bio-diversity protection law, quarantine regulations, bio-safety regulations, etc.

[6] The TRIPS Agreement requires patenting of micro-organisms, the scope of which is not defined. But it leaves each member country to protect new plant varieties (i.e. seeds and other forms of propagating material) either by patents or by an effective *sui generis* system or by a combination of both. It is therefore open to us not to allow patents, but to establish a system of `Plant Breeders' Rights' to give protection to the breeders of new plant varieties.

[7] Since this discussion paper is limited to examining the implications of Articles 70.8 and 70.9 of the TRIPS Agreement, it does not deal with the implications of the Agreement in the other areas. It is proposed to bring out a separate paper(s) dealing with the implications of the TRIPS Agreement in the three areas mentioned in para 2.5.

[8] For example, the Pharmaceutical Manufacturers Association (PMA) of America claims (quoting a February 1993 report of the United States Congressional Office of Technology Assessment), that it costs on an average US $ 359 million to get one new medicine from the laboratory to the pharmacist's shelf (*New Drug Approvals in 1993*, PMA, January 1994). *The Economist*, London had quoted a figure of US $ 230 million in this regard.

[9] The TRIPS Agreement subsumes Articles 1 to 12 and 19 of the Paris Convention of Industrial Property. By virtue of Article 4 C(I) of the Paris Convention, an applicant for a patent enjoys a right of priority for 12 months from the date of filing in another member country.

[10] Since Article 70.8 envisages the creation of a mechanism for receiving a product patent application and its being locked-up without examination till the law is amended to give a product patent, the mechanism has been colloquially called the "mail-box" mechanism.

[11] *International Herald Tribune*, January 18-19, 1992. For ready reference, see Annex 3.

[12] "Drug Development and Approval Process", in *New Drug Approvals in 1993,* PMA, January 1994. For ready reference, see Annex 4.

[13] As stated in endnote 7 above, this paper is limited to an examination of Articles 70.8 and 70.9 of the TRIPS Agreement. The implications and management of the product patent system are proposed to be analysed in a further discussion paper(s).

## Annex 1

**New Patent Drugs Introduced in the Indian Market in the five Calendar years 1994 to 1998**

| S. No. | Generic Name of Drug | Year of Introduction in | | Therapeutic Category of Drug |
|---|---|---|---|---|
| | | Indian Market | World Market | |
| (1) | (2) | 3 (a) | 3 (b) | (4) |
| 1 | Azithromycin | 1994 | 1988 | Antibiotic |
| 2 | Cefixime | 1994 | 1987 | Antibiotic |
| 3 | Lomefloxacin | 1994 | 1989 | Antibiotic |
| 4 | Mometasone furoate | 1994 | 1987 | Anti-inflammatory, topical |
| 5 | Ondansetron Hcl | 1994 | 1990 | Antiemetic |
| 6 | Ramipril | 1994 | 1989 | Anti-hypertensive |
| 7 | Salmeterol hydroxy-naphthoate | 1994 | 1990 | Bronchodilator |
| 8 | Cavulanic Acid (with amoxycillin) | 1994 | 1982 | |
| 9 | Cefbuperazone sodium | 1994 | 1985 | Antibiotic |
| 10 | Esmolol Hcl | 1995 | 1987 | Anti-arythmic |
| 11 | Itraconazole | 1995 | 1988 | Antifungal |
| 12 | Lansoprazole | 1995 | 1992 | Antiulcer |
| 13 | Lavastatin | 1995 | 1997 | Hypocholestrolemic |
| 14 | Clarithromycin | 1995 | 1990 | Antibiotic |
| 15 | Benidipine Hcl | 1996 | 1991 | Anti-hypertensive |
| 16 | Finasteride | 1996 | 1992 | 5α-Reductable Inhibitor |
| 17 | Fluticasone proprionate | 1996 | 1990 | Anti-inflammatory |
| 18 | Soar floxacin | 1996 | 1993 | |
| 19 | Sumatriptan succinate | 1996 | 1991 | Antimigraine |
| 20 | Terbinafine Hcl | 1996 | 1991 | Antifungal |
| 21 | Terconazole | 1996 | 1983 | Antifungal |
| 22 | Artesunate | 1996 | 1996 | |
| 23 | Alendronate | 1997 | N.A. | |
| 24 | Benazepril Hcl | 1997 | 1990 | Anti-hypertensive |
| 25 | Enoxaparin | 1997 | 1987 | Anti-thrombatic |
| 26 | Lacidipine | 1997 | 1991 | Anti-hypertensive |
| 27 | Mexazolam | 1997 | 1984 | Anxiolytic |
| 28 | Nicorandil | 1997 | 1984 | Coronary vasodilator |
| 29 | Reviparin Sodium | 1997 | 1993 | |
| 30 | Risperidone | 1997 | 1993 | |
| 31 | Simvastatin | 1997 | 1988 | Hypo-cholestrolemic |

| | | | | |
|---|---|---|---|---|
| 32 | Zidovudine | 1997 | 1987 | Anti-viral |
| 33 | Calcipotriol | 1998 | 1991 | Antipsoriatic |
| 34 | Cefpirome Sulfate | 1998 | 1992 | Antibiotic |
| 35 | Fexefenadine | 1998 | 1996 | |
| 36 | Lamivudine | 1998 | 1995 | |
| 37 | Lamotrigine | 1998 | 1990 | Anticonvulsant |
| 38 | Losartan | 1998 | 1994 | |
| 39 | Sertraline Hcl | 1998 | 1990 | Antidepressant |

*Source* : ARMC, Vol. 29, pp. 379-388, on "Cumulative NCE Introduction Index 1983-1992" for cols. 3(b) and 4, and Industry sources for the whole table.

## Annex 2

### PART VI : TRANSITIONAL ARRANGEMENTS

Article 65

**Transitional Arrangements**

1. Subject to the provisions of paragraphs 2, 3 and 4 below, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the Agreement Establishing the MTO.

2. Any developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1 above, of the provisions of this Agreement other than Articles 3, 4 and 5 of Part I.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws, may also benefit from a period of delay as foreseen in paragraph 2 above.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2 above, it may delay the application of the provisions on product patents of Section 5 of Part II of this Agreement to such areas of technology for an additional period of five years.

5. Any Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 above shall ensure that any changes in its domestic laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

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Article 70.8 and 70.9

8. Where a Member does not make available as of the date of entry into force of the Agreement Establishing the MTO patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(i) notwithstanding the provisions of Part VI above, provide as from the date of entry into force of the Agreement Establishing the MTO a means by which applications for patents for such inventions can be filed;

(ii) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application;

(iii) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in sub-paragraph (ii) above.

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8 (i) above, exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI above, for a period of five years after obtaining market approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, providedthat, subsequent to the entry into force of the Agreement Establishing the MTO, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

## Annex 3

INTERNATIONAL HERALD TRIBUTE

January 18-19, 1992

# U.S. and China
# Sign Agreement

## On Copyrights

By Keith Bradsher

**New York Times Service**

WASHINGTON – The United States and China signed an agreement Friday intended to provide greater protection for American pharmaceuticals, computer software, books and music recordings against illegal copying in China. Settlement of the eight-month dispute averted what had threatened to become a trade war.

China essentially agreed to adopt most international standards for foreign inventions, and will enact laws that extend the duration and scope of patent, copyright and trade-secret protections. American trade associations have contended that the copying has resulted in $400 million in annual losses from violated pharmaceutical patents and $419 million in annual losses from violations of copyrights on computer software, books and music recordings.

The Bush administration threatened in November to impose new tariffs of up to 100 percent on goods from China in retaliation for their refusal to honor and enforce patent rights.

Chinese authorities had warned last week that if the United States went forward with these trade sanctions, China might retaliate by raising the tariffs on American planes, corn, steel and other products that are exported to China.

The International Intellectual Property Alliance, a Washington-based trade group representing industries with trade concerns, said Thursday's deal was acceptable.

"If they implement what they have agreed upon in good faith, we will begin to see a major shift on the ground for our stuff beginning next year," said Eric H. Smith, the group's general counsel.

A senior U.S. official said the Pharmaceutical Manufacturers Association had agreed to endorse the pact.
In another development Thursday, China agreed to allow two American companies to compete directly with Chinese rivals in shipping the nation's cargo (Page 11).
Timothy A. O'Leary, a spokesman for the U.S. trade representative, Carla A. Hills, said it was a coincidence that both deals came on the same day.

In the deal on copying, China agreed to join the Berne Convention on copyrights on Oct. 15 and the Geneva Phonograms Convention in June, 1993.

China also agreed to extend patent protection to 20 years from 15 years and to eliminate most requirements that force multinationals to license production of their inventions to local Chinese companies instead of exporting directly to China, said the official, who insisted on anonymity.

The last issue settled concerned the protection of pharmaceutical and other chemical products already patented but not yet available for sale. The issue was especially important for the pharmaceutical industry because 10 years of safety tests are typically needed after a product is patented.

After initially insisting that only future inventions be covered, the Chinese agreed to protect products patented since Jan. 1, 1986, the senior American official said.

The United States had threatened to impose high tariffs on up to $1.5 billion worth of Chinese exports to retaliate for the losses of American royalties caused by illegal copying, although Mrs. Hills had said that a final figure covering $750 million of Chinese goods would be "in the ballpark".

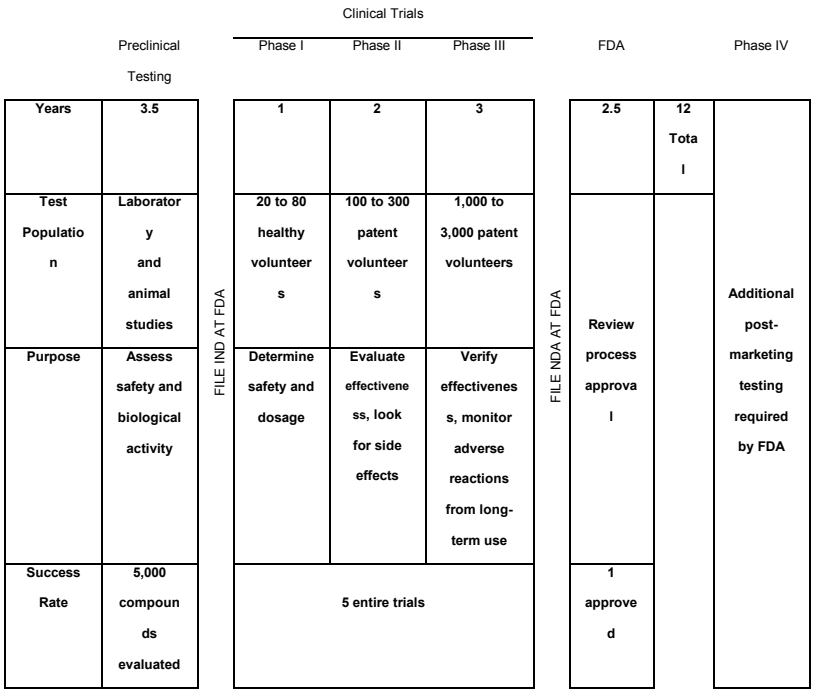
But China threatened to impose up to $1.2 billion in retaliatory sanctions if the United States acted, and the senior American trade official said last week that he believed the Chinese threat.

A trade war with China would have been politically awkward for the administration during an election year, particularly given President George Bush's insistence that China should maintain its access to the U.S. market, without conditions.

## Annex 4

DRUG DEVELOPMENT AND APPROVAL PROCESS

It takes 12 years on average for an experimental drug to travel from lab to medicine chest Only five in 5,000 compounds that enter preclinical testing make it to human testing One of these five tested in people is approved



*The Drug Development and Approval Process*

**By Dale E. Wierenga, Ph.D. and C. Robert Eaton**

***Office of Research and Development***

***Pharmaceutical Manufacturers Association***

The U.S. system of new drug approvals is perhaps the most rigorous in the world. On average, it costs a company $ 359 million to get one new medicine from the laboratory to the pharmacist's shelf, according to a February 1993 report by the Congressional Office of Technology Assessment.

It takes 12 years on average for an experimental drug to travel from lab to medicine chest. Only five in 5,000 compounds that enter preclinical testing make it to human testing. And only one of those five is approved.

New medicines are developed as follows :

***Preclinical Testing.*** A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests take approximately three and one-half years.

***Investigational New Drug Application (IND).*** After completing pre-clinical testing, the company files an IND with FDA to begin to test the drug in people. The IND becomes effective if FDA does not disapprove it within 30 days. The IND shows results of previous experiments : how, where and by whom the new studies will be conducted : the chemical structure of the compound : how it is thought to work in the body; any toxic effects found in the animal studies: and how the compound is manufactured. In addition, the IND must be reviewed and approved by the Institutional Review Board where the studies will be conducted, and progress reports on clinical trials must be submitted at least annually to FDA.

***Clinical Trials, Phase I.*** These tests take about a year and involve about 20 to 80 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action.

***Clinical Trials, Phase II.*** In this phase, controlled studies of approximately 100 to 300 volunteer patients (people with the disease) assess the drug's effectiveness. These studies take about two years.

***Clinical Trials, Phase III.*** This phase lasts about three years and usually involves 1,000 to 3,000 patients in clinics and hospitals. Physicians monitor patients closely to determine efficacy and identify adverse reactions.

***New Drug Application (NDA)***. Following the completion of all three phases of clinical trials, the company analyzes all of the data and files an NDA with FDA if the data successfully demonstrate safety and effectiveness. The NDA must contain all of the scientific information that the company has gathered. NDAs typically run 100,000 pages or more. By law, FDA is allowed six months to review an NDA. In almost all cases, the period between the first submission of an NDA and final FDA approval exceeds that limit.

The average NDA review time for new molecular entities approved in 1993 was 26.5 months.

***Approval.*** Once FDA approves the NDA, the new medicine becomes available for physicians to prescribe. The company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional studies (Phase IV) to evaluate long-term effects.

Discovering and developing safe and effective new medicines is a long, difficult and expensive process. The research based pharmaceutical industry will invest $ 13.8 billion in research and development this year.