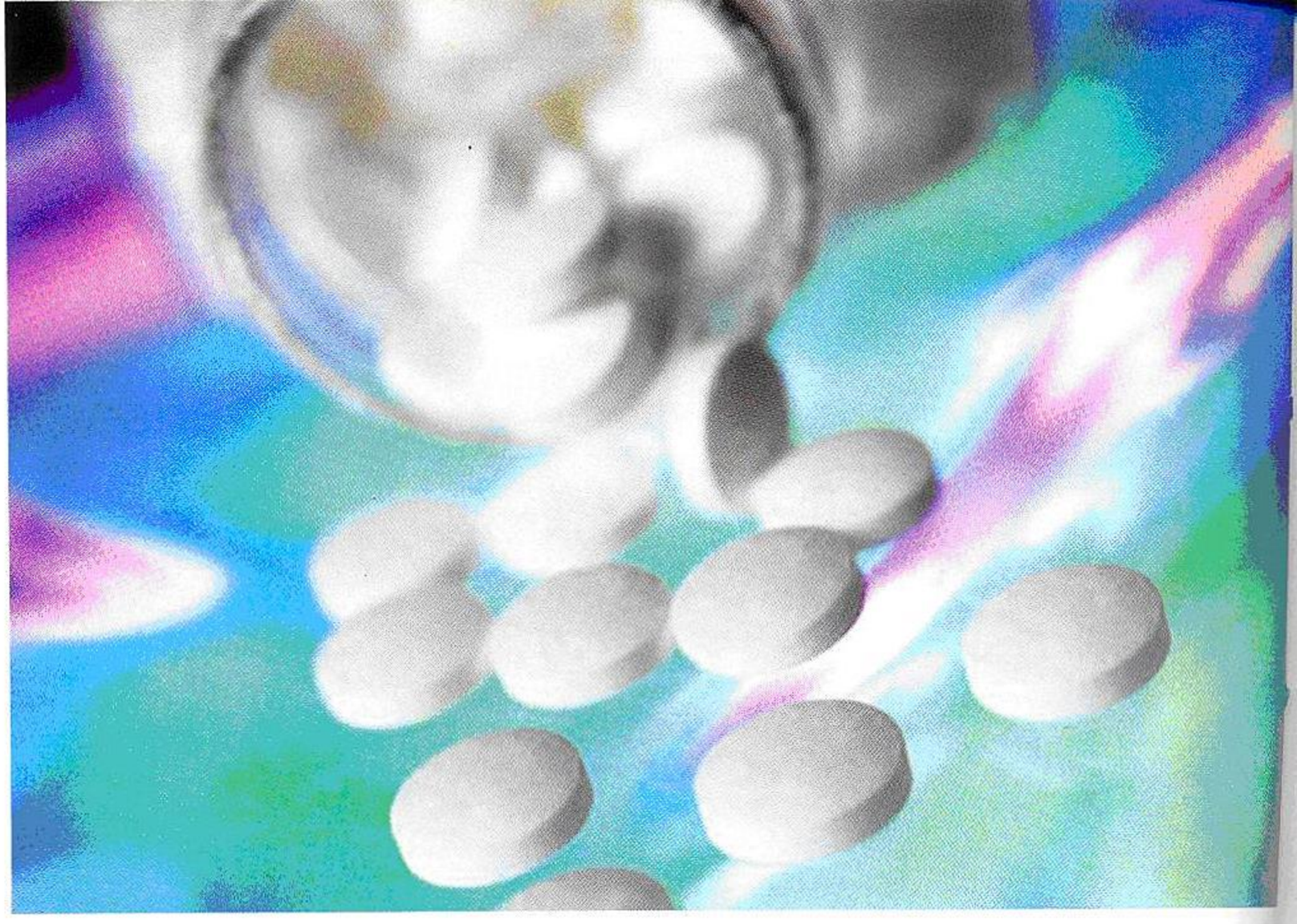


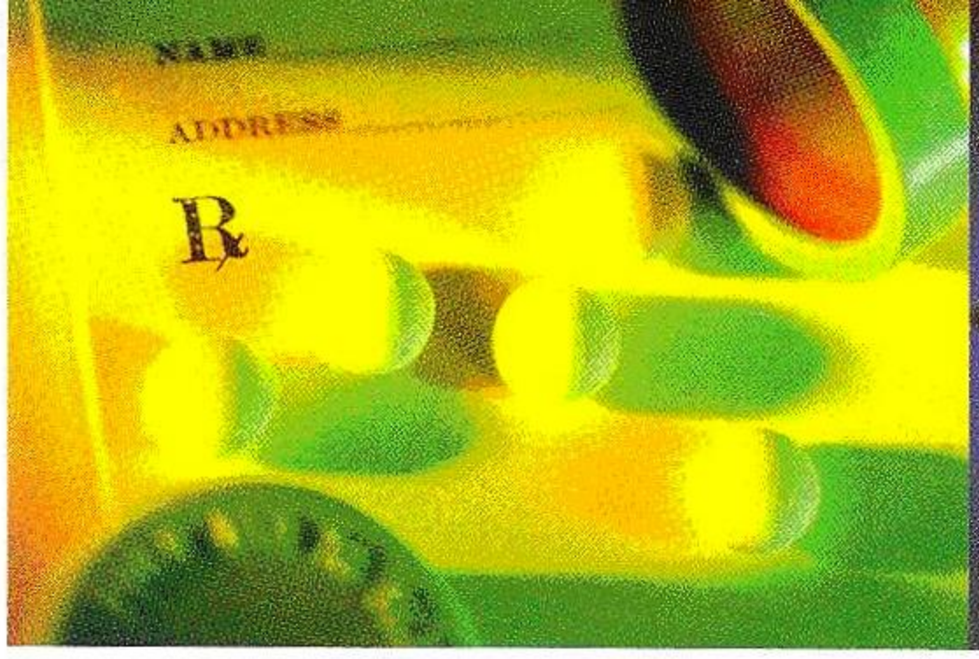
Indian Patent Act & its Impact on Pharma Industry

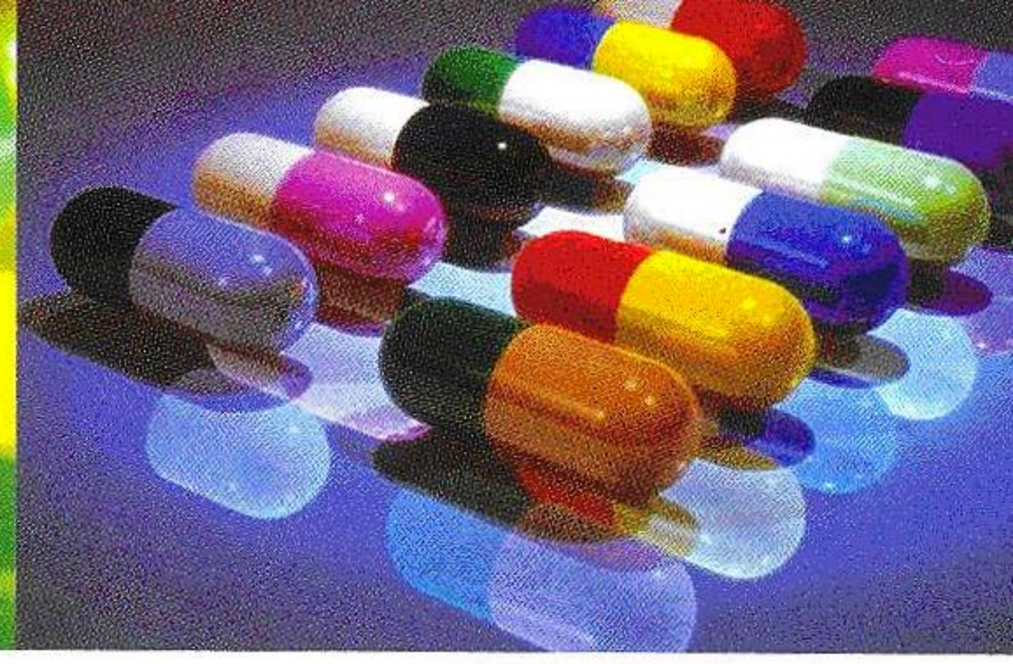
Dr Gopakumar G Nair

India has become self-reliant in manufacturing of formulations and emerged as one of the leading manufacturers of bulk drugs globally. The Indian drug prices emerged as the lowest in the world, in most therapeutic segments.

The Pharma Industry in India owes a lot to the architects of the Patent Act, 1970, which abolished product patents in the fields of foods, medicines and agrochemicals, and introduced the provision for "licence of right" and fixed a reduced patent life of 7 years from the date of application or 5 years from date of sealing whichever is less for the above essential categories as against a normal period of 14 years for general items. Indian Pharma Industry made slow but steady progress thereafter, became a net exporter from a large importer of medicines and active ingredients (bulk drugs) in about the next 20 years. India also became self-reliant in manufacture of formulations (dosage forms) and emerged as one of the leading manufacturers of bulk drugs (actives) globally. During this period, partially with government intervention through five consecutive DPCO's (Drug Price Control Orders) and more significantly with voluntary price reductions compelled by market competition and corporate strategies (as by Dr. Reddy's, Lupin, Cipla, etc.), the Indian drug prices emerged as the lowest in the world, in most therapeutic segments. The fact that India is the 4th largest in volume and 14th in value terms globally, speaks volumes for Indian drug prices.

From a mere few hundred manufacturers in the early seventies, the number of drug manufacturers has grown to more than 10,000. At the same time, Indian brands have emerged as market leaders. Ranbaxy's Calmpose (against Valium of Roche) and JB Chemical's (then Unique) Metrogyl (against Flagyl) are few examples. The (then) Lyka introduced Ampilin had become an instant success. All these brands became household names. This led to a reversal of fortunes. While in 1970, the top 6 to 7 pharma companies in India were MNCs, by 1990, 6 to 7 Indian Companies adorned the top 10. A similar reversal of ratio took place for the

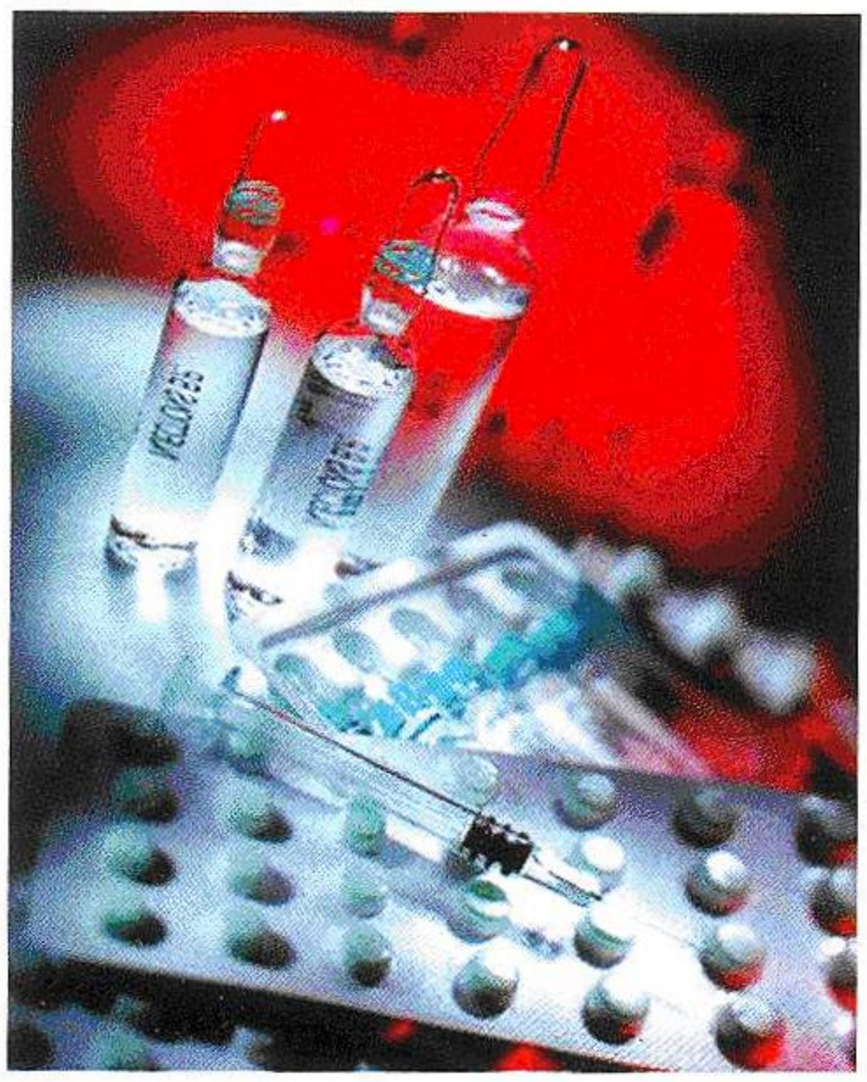




top 10 brands also.

While this scenario was unfolding in the Indian domestic market, all was not quiet on the global MNC front. Hurt by such developments in progressive developing countries, leading developed countries, pushed by Big Pharma, were formulating strategies to turnaround their fortunes once again or "to put the clock back" to the sixties, in the developing markets.

The international trade was governed by a purely equitable body called GATT (General Agreement on Trade and Tariff). GATT was doing what was expected of it, rather quietly, but efficiently. Around the mid-eighties, (after closed-door preparations from early eighties) a proposal was brought into GATT at Uruguay (hence now known as the Uruguay Round), to include Intellectual Property Rights into GATT and give GATT a new "body and soul". Most developing countries were taken by surprise. They didn't have any domestic expertise on IPR. In spite of this there was stiff opposition from few leading developing countries (Russia and China were not included at that time). It was then that Dr. Arthur Dunkel emerged with his "Dunkel Draft" as a compromise proposal (this was at that time nick-named DDT, Dunkel Draft Treaty). After protracted negotiations, this draft emerged as TRIPs (Trade Related Intellectual Property Rights) while GATT became WTO (World Trade Organization).



WTO was established on 1-1-1995 at the conclusion of the Uruguay Round of multilateral trade negotiations. India became one of the founder-members. Under the WTO, a wide ranging system of agreements and rules for governing international trade were concluded. TRIPs Agreement is one of the agreements making up the integrated WTO system of trade rules. There are others like Technical Barriers to Trade (TBT) Rules of Origin (RO), Sanitary and Phytosanitary Measures (SPS) and others.

TRIPs expects member countries to put in place a harmonized system of intellectual Properties (patents, trademarks, copyrights, designs, etc). While industrialized nations had to comply within one year, the developing counties were given five years to comply. Those developing countries who did not have a full product patent regime in place (prior to 1-1-1995) were allowed a further period of 5 years to amend their national laws to minimum standards prescribed by TRIPs (this is how India was obliged to bring in product patent regime and other standards latest by 1-1- 2005). However, TRIPs provides for flexibilities for each member country to have provisions for national needs and priorities, like public health and nutrition, and also to deal with emergencies and abuse of IP [(through Art. 2 link to Paris Convention (PC)]. The LDCs (least developed countries) were allowed time up to 2006, but later this period got extended to 2016 at Doha Round.

TRIPs provides for flexibilities for each member country to have provisions for national needs and priorities, like public health and nutrition, and also to deal with emergencies and abuse of IP.

Between 1995 and 2005, India amended the Trademark Act (1999), Copyright act, 1957; India also has come up with three Patent Amendments to comply with TRIPs provisions. India also became a member of Paris Convention (PC) and Patent Co-operation Treaty (PCT) in December 1998. The salient features of the three patent amendments are as follows.

I. Patents (Amendment) Act,1999 – 1st Amendment (effective from 1-1-1995)

1. It provides for filing of product patent applications related to pharmaceutical and

agro-chemicals in the mailbox from 1.1.95 to be taken up for examination on or after 1.1.2005 (or when product patent regime comes into place).

2. Establishes a system for grant of Exclusive Marketing Right (EMR) on these applications, subject to qualifying conditions.

3. Provisions for Compulsory licenses modified, deleting licence or right, etc.

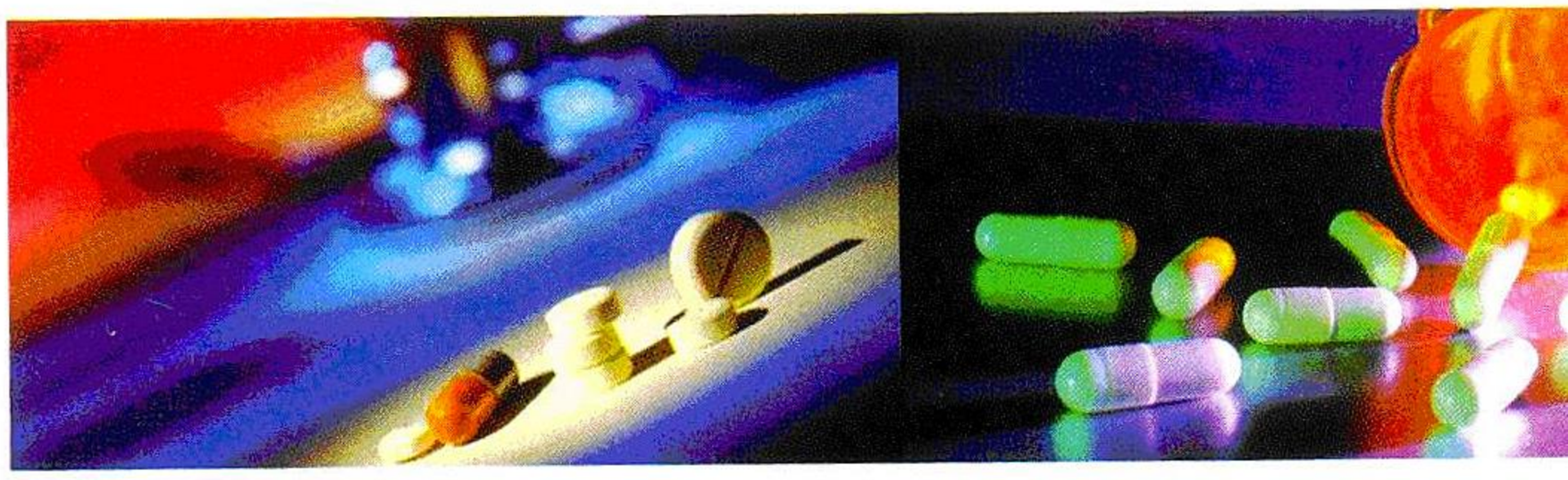
II. Patents (Amendment) Act, 2003 - 2nd Amendment (effective from 20-5-2003)

Salient features of the Patents (Amendment) Act, 2002

1. Term of every patent got extended to 20 years from date of filing.

2. Definition of "Invention" was amended. "A new product or process involving inventive step and capable of industrial application".

The new amendment is very liberal and easy to meet the requirement. "Technical advance or economic significance or both" will bring inventive step which when added to "novelty" will make an invention patentable.



3. A method or process of testing during the process of manufacture - patentable.

4. Process defined, U/S 3(i) in case of plants, are now patentable while a process for diagnostic and therapeutic are non patentable.

5. A list of Authorized Depository Institutions notified for depositing the biological materials mentioned in the specification at the time of filing a patent application (Budapest Treaty).

6. The source of Geographical origin of the biological material used in invention is required to be disclosed in the specification.

7. 18 months publication has been introduced, therefore, every patent (except in which a secrecy direction is given U/S 35) will now be published just after 18 months from the date of filing/ priority and will be open for public on payment.

8. A request for examination system has been introduced and therefore all the patent applications in which First Examination Report has not been issued on or before 19th May, 2003 will now be examined U/S 12 only after filing a request for examination on Form–19 with prescribed fee.

9. In case the application has been filed before the commencement of this Act, the request shall be made within a period of twelve months from the date of commencement of the Act, i.e., 20th May 2003 or 48 months from the date of application, whichever is later.

10. Provision for filing request for examination by any other interested person (other than applicant) introduced.

11. Provision for the withdrawal of application by applicant any time before grant introduced.

12. Time for putting the application in order for acceptance U/S 21 reduced from 15/ 18 months to 12 months.

13. Ground of opposition U/S 25 as well as revocation U/S 64 enlarged by adding following grounds:

(a) Non disclosure or wrongly mentioning the source of geographical origin of biological material used for invention;

(b) Anticipation having regard to the knowledge, oral or otherwise, available within local or indigenous community in India or elsewhere.

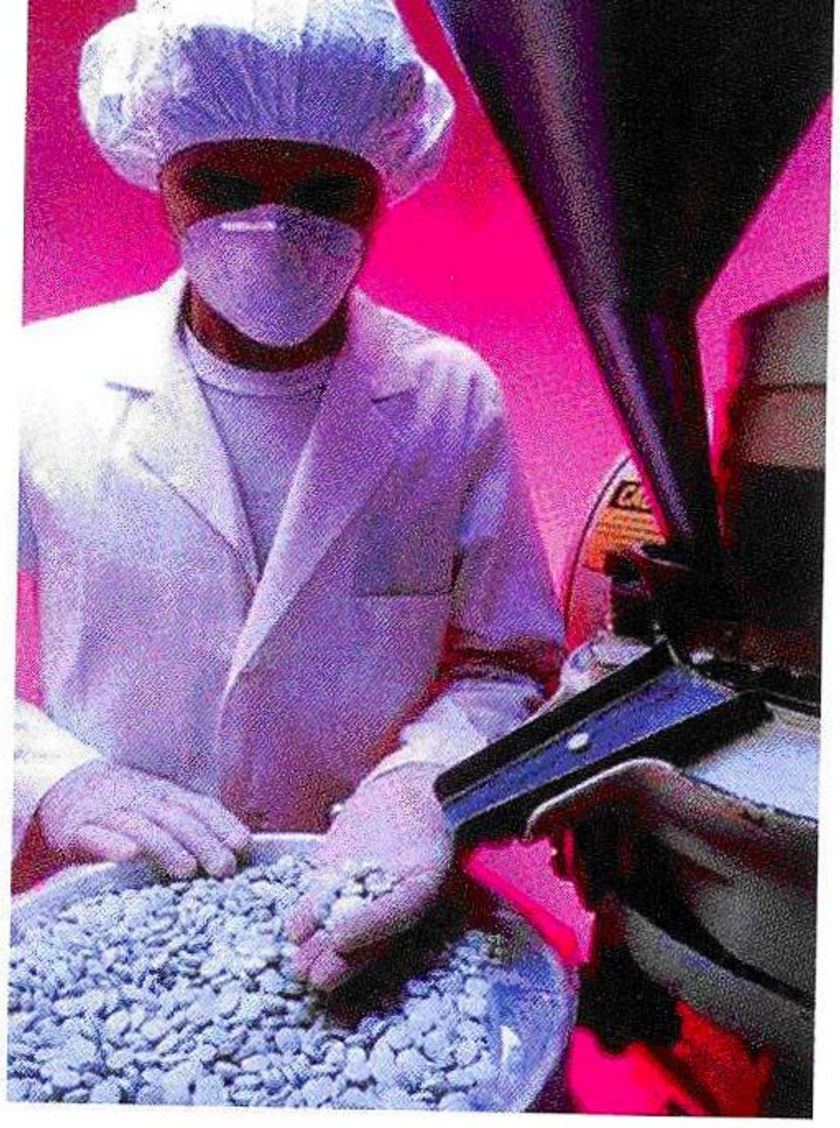
14. Prohibition of filing patent applications outside India for inventions related to the fields of defence purposes or atomic energy reintroduced.

15. Opposition Proceedings U/S 25 have been simplified and shortened.

16. Various PCT provisions incorporated into the Rules, 2003.

III. Patents (Amendment) Act, 2005 - 3rd Amendment (effective from 1-1-2005)

The third amendment was initially brought in



Being dragged to WTO's Dispute Settlement Forum for a sure defeat is something that India can ill-afford. That could deprive India the already incorporated flexibilities also, if subjected to a fine comb.

as an Ordinance on 26th December, 2004 followed by Patent (Amendment) Rules, 2005. The Ordinance when presented to Parliament as a Bill was further amended as on April 4, 2005 (majority of provisions becoming effective from 1-1-2005).

The Salient features with interpretation are as follows:

It was very difficult to claim "inventive step" in post May 2003 (2nd Amendment).

The new amendment is very liberal and easy to meet the requirement. "Technical advance or economic significance or both" will bring inventive step which when added to "novelty" will make an invention patentable.

1. A new definition of "new invention" is introduced which reads as follows.

(l) *"new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, that is, the subject matter has not fallen in public domain or that it is not form part of the state of the art.*

Effect: This has no meaning or effect as there is no mention of "new invention" anywhere in the Act or Rules. This will remain as a "definition" with no use/benefit/advantage, unless and until Act or Rules are further amended.

2. Section 3 (d) has been amended (Ordinance has been amended by the Bill). This is the single-most important change which is favourable to the Domestic manufacturers.

3(d) read earlier as follows:

3(d) *the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;*

Now, 3(d) read as follows:

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

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of know substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Effect: Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and derivatives of known substances are now not patentable, unless they have more proven efficacy.

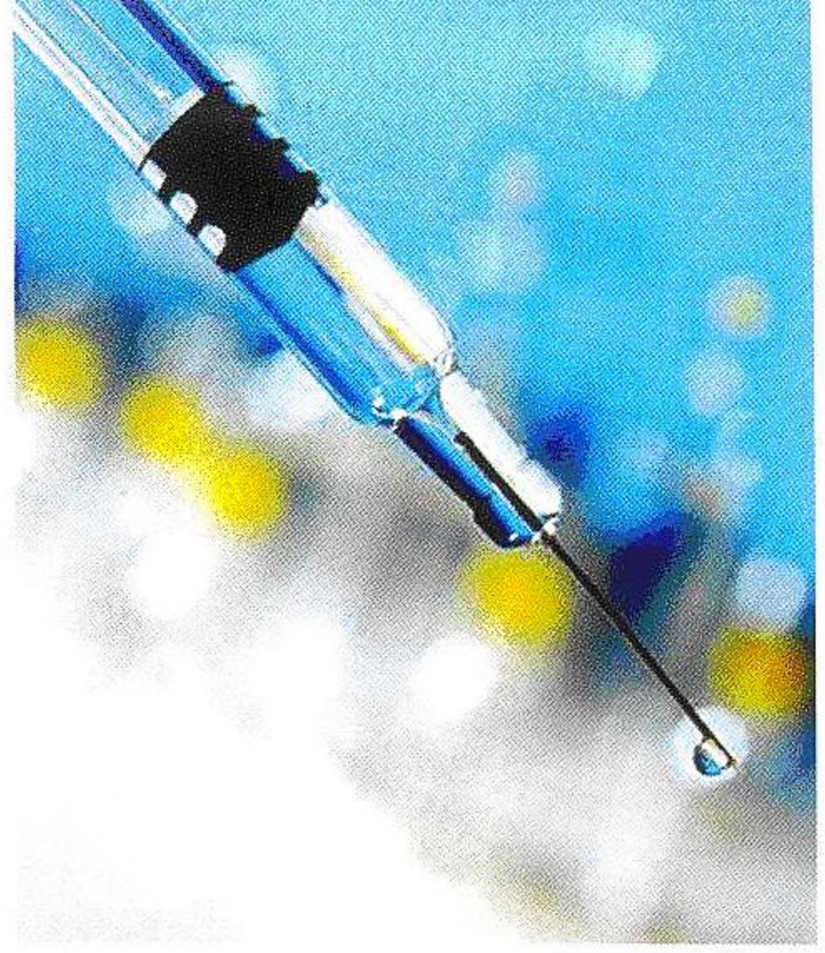
3. No patent infringement action can be initiated for any NCE molecules or product, for which product patents will be granted after 1.1.2005, if any manufacturer has introduced that product already in India. However, the inventor (product patent holder) can receive REASONABLE ROYALTY from the manufacturer.

4. Pre-grant representation is now strengthened by providing for personal hearing by Controller, before disposing the application. The grounds of opposition in pre-grant stage has been expanded and strengthened by making the grounds same as post-grant opposition or same provisions in Sec. 25.

Further the time available for an interested person to oppose (at pre-grant level) has been increased to 6 months (over and above 1 year for post-grant opposition).

This means that, there are multiple opportunities to oppose the grant of a patent.

1) Pre-grant opposition - 6 months time from publication u/s11A



2) Post-grant opposition - 12 months for opposition (from date of grant)

3) Patent Revocation - in High Court (anytime)

5. Export under compulsory license has been made easier and simpler. Formulations under valid patent can also be exported to LDCs etc. if the export order is authorized or approved by the Government of that country in which case compulsory licence will be issued in India.

On the policy front, India has stretched itself sufficiently within a TRIPs compliant regime. Anything more than this current status, could invite avoidable acrimony and confrontation. Being dragged to WTO's Dispute Settlement Forum for a sure defeat is something that India can ill-afford. That could deprive India the already incorporated flexibilities also, if subjected to a fine comb.

On the procedural aspects there is much to be done. There is cause for a lot of concern and confusion in the operational provisions, many of which could be and may be challenged legally (which also is avoidable).

The overall impact of the finally amended Patent Act, 1970 in its current format is as follows:

01. Post 1.1.2005, Indian companies should verify product patent status in India for every (now) patented or patentable molecule. Every molecule which is in the mailbox which overcomes the "Explanation to Section 3(d)", could get a product patent granted to the applicant. If this molecule has not already been introduced in India prior to 1.1.2005, the Indian company will not be able to get away with paying "reasonable" (1 to 4%?) royalties. The threat of damages, penalties, loss of profits loom large, if litigated. To prevent such a tricky situation, it will be prudent on the part of the Indian companies to examine pending mailbox (MNC) applications and oppose those which are likely to impact them adversely.

02. Once product patents are granted, it is worthwhile watching and waiting to take appropriate steps to prepare for a compulsory licence application, which could be considered after 3 years of grant.

03. Exhaustively examine every possibility of landing up with an export order from an LDC (least developed country) or a country where a legal order can be placed for a patented product from a foreign country (through a local compulsory licence in that country or a valid import permit or the like) wherein that item can be taken up for export production (commercially) in India and can be exported to that country.

04. Continue to develop processes for actives and dosage forms, irrespective of patent status, which is possible under Sec. 107 A (a) as well as under Sec. 47 (3).

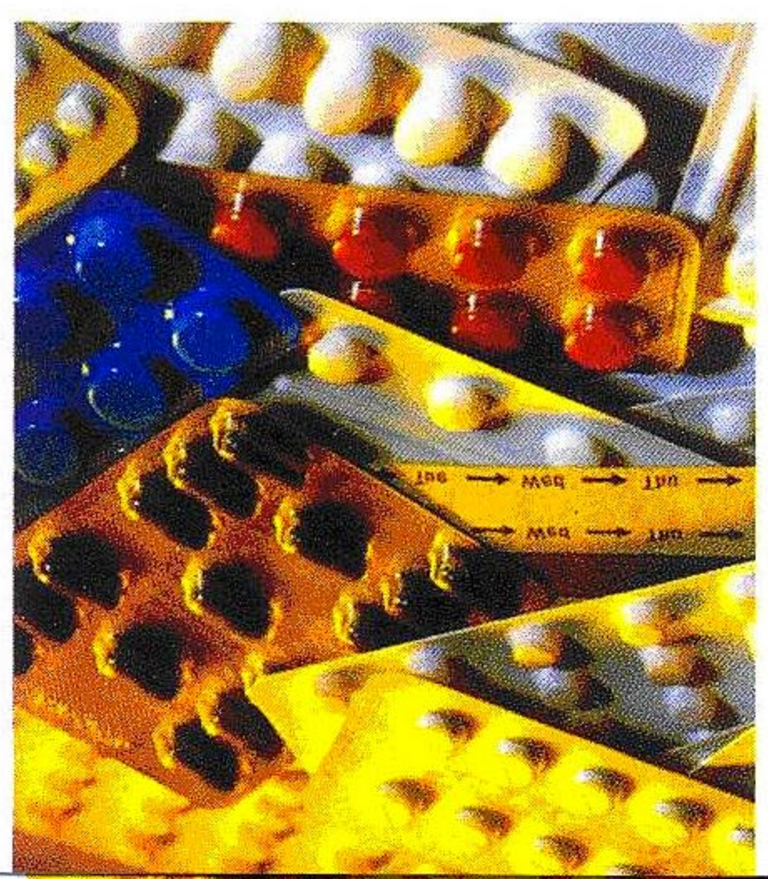
05. Watch out for "nonworking" of granted patents in India.

06. All said and done, comply and honour all Intellectual Properties both in India and overseas meticulously.

07. Provide for complete confidentiality in-house for any IP that is received from alliance partner or contract research or contract manufacturing partner or principal.

08. Be a "shark" in-house for IP practice and preferably be a "dolphin" in patent litigation, i.e., wherever possible and practicable, opt for a negotiated settlement of patent disputes and infringement suits (rather than), in preference to a protracted litigation.

The opportunities as well as threats are never ending. With a positive mindset and passion for value-creation and IP Asset-building, any organization can convert threats into opportunities.



09. When introducing a new product in an overseas country, generic or otherwise, be assured with a "non-infringing certification" from a patent attorney of repute.

10. Unless you are a seasoned player, already cash rich from patent licensing and commercializing, do not opt for a patent challenge (Para IV in USA, for example), go for a Para III filing.

11. Do a lot of networking, licensing-in and if equipped, licensing out; alliance are in, avoid patent litigation unless you are sure to win (which all litigants are on both sides – based on confidence provided by the legal pundits).

12. Ensure that every Technology Transfer Agreements, Licensing Agreements, Confidentiality and Non-Disclosure Agreements and Non-compete Agreements are examined properly before signing them. Be on the look out for soft exit clauses, in case of extreme exigencies.

13. Enlighten the organization as a whole, not only on TRIPs, IP laws including Patent Law of India and also the

overseas countries of commercial interest, but also the various other WTO Agreements, Rules and Systems.

14. Train "people" – intellectual property is people-power – and update them in-house continually. Participate in Policy-making to have a IP/Patent policy for the country of your manufacturing and commercial interest.

The opportunities as well as threats are never ending. With a positive mindset and passion for value-creation and IP Asset-building, any organization can convert threats into opportunities. Next few years, decades and centuries are India's. India is poised to regain in its lost glories. Be a party to it, Let us party together for "GOING GLOBAL"!

(Writer's e-mail address: gopanair@gnaipr.net)

Next few years, decades and centuries are India's. India is poised to regain in its lost glories. Be a party to it, Let us party together for "GOING GLOBAL"!