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From the Director's Desk

Prabir Sengupta

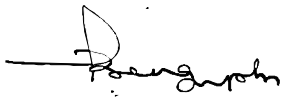
The Ordinance for amending the Indian Patents Act brought in late December 2004 is designed to make the legislation consistent with the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This is the third amendment of patent law which India was required to make to fulfil its obligations under the TRIPS Agreement.

The most significant feature of this amendment is the introduction of a product patent regime covering the area of pharmaceuticals replacing the hitherto existing process patent regime. This means product patent applications have to be accepted and examined in India from January 1, 2005.

The Ordinance has generated a lot of debate in India regarding its contents and long-term implications particularly in respect of access to medicines at affordable prices. It has been argued that in the absence of adequate safeguards, the introduction of the product patent regime would weaken the considerable advantages that India has acquired over the years in the production of low cost generics. As a result, it would strengthen the global players who have sufficient monopoly in the markets of patented products. This product patent regime, it has been contended, will indirectly affect the accessibility and affordability of consumers in India by creating a regime which may result in an upward movement of pricing of products, and this in turn would dampen the overall spirit of Doha Declaration on TRIPS Agreement and Public Health.

A second issue has been raised in relation to the pre- and post-grant opposition to patent. Although the Ordinance introduces post-grant opposition akin to the practice followed by the European Patent Office, it also includes provisions for pre-grant opposition, which can improve the quality of patents granted in India. The provisions spelt out in the pre-grant opposition may need strengthening to make them more effective.

Experts have opined that the new patent regime should take into account various welfare measures such as cost and competition related issues. They have rightly argued that in a country like India, the patent regime should strike a balance between private property rights and the larger public good. The present issue covers the various implications of this important subject.



The Third Amendment of the Indian Patents Act

*Biswajit Dhar**

Introduction

INDIA'S commitment to implement the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) fully required three sets of amendments to the country's Patents Act. The first amendment was introduced in 1999 to put in place a mechanism for accepting product patent applications covering pharma-ceutical and agricultural chemicals from 1 January 1995 (better known as the mailbox provisions) and to provide exclusive marketing rights if certain conditions are fulfilled. The second amendment was introduced in 2002 to bring the Indian Patents Act in conformity with all the provisions included in Section 5 of the TRIPs Agreement relating to patents, barring a solitary exception. This exception, viz. introduction of product patents in the area of chemicals, pharmaceuticals, agricultural chemicals and food, is the principal subject matter of the third amendment, the third deadline for meeting which was 1 January 2005.

In order to fulfil its commitment to fully implement the TRIPs Agreement, the Government had brought the Patents (Amendment) Bill, 2003[1] before the 13th Lok Sabha in December 2003. With the dissolution of 13th Lok Sabha, this bill had lapsed. When the UPA Government took up the issue of amending the Patents Act before the end of 1 January 2005 deadline, it decided to consider the bill that the NDA Government had presented. However, with no decision in sight, the Government decided to issue an ordinance (henceforth "the ordinance") for introducing the amendments to the Patents Act 1970.

Although this amendment to the Indian Patents Act required introduction of product patents in areas that were thus far covered by process patents, the ordinance proposes several other changes in the existing legislation. In our view, the provisions included in the ordinance are of two types. The *first* includes provisions that are mandatory keeping in view the TRIPs commitments, while the *second* set of proposals includes those that, in our view, would not serve the interests of the country well. There is a third dimension to the ordinance, and this is the set of issues that needs to be considered when the ordinance is replaced by the amending Act. This dimension, in our view, is significant since we feel that the inclusion of these aspects in the amending legislation is essential if the patent system is to be used for realizing the larger public interest objectives. This paper provides a brief commentary on the above-mentioned aspects of the ordinance.

Introducing Product Patents

The ordinance provides for this mandatory requirement for fulfilling India's commitments under TRIPs Agreement through the removal of Section 5(1) of the Patents Act 1970, which provides for process patents in this field, and also by removing the definition of food (Section 2(1) (g) of the earlier Act). This means that from 1 January 2005 product patent applications have to be accepted and examined in India. Included in these product patent applications would be those applications that were made since 1995 using the "mailbox" provisions. The "mailbox" provisions were introduced in the Patents Act through the first amendment undertaken in 1999 in order to fulfil the condition imposed in Article 70 of the TRIPs Agreement (the so-called "Transitional Arrangements"). The "Transitional Arrangements" were in the nature of a trade-off for the longer period that India could enjoy for introducing product patents in areas that were hitherto covered by process patents.[2]

The "Transitional Arrangements" required India to introduce two provisions in its Patents Act. Article 70.8 of the TRIPs Agreement required India to provide "a means" by which product patent applications can be

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filed from 1 January 1995. If the products figuring in these applications were granted a patent in any of the WTO member countries and the products were granted marketing approval in any of the WTO member countries, then, according to Article 70.9, five years exclusive marketing rights (EMRs) had to be granted by India before the patent on the product was either granted or rejected in India. The first amendment of the Patents Act 1970 introduced the requirements under the "transitional arrangements through Section 5(2), which allowed product patent applications to be filed, while Chapter IVA provided for the grant of EMRs. With the end of the transitional period for India, after the ordinance became effective on 1 January 2005, both these provisions had to be repealed, which has been provided for in the ordinance. However, an additional provision has been included in Section 11B of the Act to take into consideration the rights of the applicants whose request for the grant of EMRs was made before the enforcement of the ordinance. This provision also ensures that the applications in respect of which EMRs have been granted before the ordinance took effect would be examined for the grant of patents in keeping with the provisions of the new Act.

One of the issues that have been raised in the context of the introduction of product patents in the area of pharmaceuticals has been that India could become a fertile ground for the grant of patents on formulations, new dosages and new usages as has been seen in countries like the US where several patents have been granted in recent years on combination and new uses of commonplace medicines like aspirin and ibuprofen.[3] The National Institute for Health Care Management of the US has commented in a recent report that "drug manufacturers patent a wide range of inventions connected with incremental modifications of their products, including minor features such as inert ingredients and the form, colour, and scoring of tablets"[4]. The Report further comments that "in some cases, these patents may discourage generic companies from trying to develop a competitive product".

Quite clearly then the grant of patents on formulations is that the markets for many of the commonly used medicines, whose original patents may have expired years or even decades earlier, remain narrow with only a small number of companies controlling them. In the absence of patents on formulations, etc. there would have been no market entry barriers for generic manufacturers, and this would have put downward pressure on prices in a significant manner.

A serious re-thinking is thus needed on the manner in which the patent system ends up granting patents on what may be termed as minor innovations.[5] The most persuasive justification for so doing is the growing concerns about access to medicines at affordable prices, particularly in the developing countries. India could have taken the lead in this regard by making appropriate changes in its Patents Act, which would have given strong signals that it is keen to prevent the grant of patents on products that should have been "generic".

Pre- *versus* Post- Grant Opposition

One of the more controversial of the proposals made in the ordinance relates to the changes that have been introduced in respect of opposition to the grant of patents. Before the introduction of this ordinance, Section 25 of the Patents Act provided for the initiation of proceedings for opposing the grant of a patent, which could be launched within four months from the date of advertisement of the acceptance of complete specification. In other words, India followed a system of pre-grant opposition. The grant of patents could be opposed on the grounds that included (i) the invention for which the patent has been claimed was publicly known or publicly used in India, (ii) the invention is obvious and does not involve an inventive step, (iii) the invention is not patentable under the Patents Act 1970, (iv) the complete specification wrongly mentions the source or geographical origin of biological material used in the invention, and (v) the invention on which the patent is claimed forms part of the traditional knowledge whether in India or elsewhere.

The ordinance introduces two sets of changes to the conditions relating to opposition to the grant of patents. *First*, the post-grant opposition has been introduced and *secondly*, provisions relating to pre-grant

opposition have been whittled down quite significantly.

Post-grant opposition, which has been provided in Section 25(3) of the Patents Act, 1970 allows any interested person to oppose the grant of a patent before the expiry of one year from the date of grant of patent. But while a change in the system of opposition has been included, the ground for opposition has been left unchanged. The grounds for pre-grant opposition in the 1970 Act have been retained in the post-grant opposition of ordinance.

Pre-grant opposition included in Section 25(1) can be made after the publication of the patent application on the ground of patentability, including novelty, inventive step and industrial application. Two other grounds for this representation have been provided, viz. non-disclosure or wrongful mentioning of the source and geographical origin of biological material used in the invention and anticipation of the invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere. Two issues need to be pointed out in the context of the changes effected in the provisions relating to opposition to patents. The *first* is that with the exception of the above-mentioned ground, all other grounds on which pre-grant opposition could have been made before the introduction of the amendment have been removed. This implies that the pre-grant opposition has been rendered specious. *Secondly*, Section 25(2), as amended through the ordinance, provides that the person making the pre-grant representation cannot be a party to the proceedings, which would weaken case of those opposing the grant of patents.

The overriding consideration for changing the system of opposition to the grant of patents has been that post-grant opposition would reduce the time period for the grant of patents in India. However, the argument for doing away with pre-grant opposition should be based on the capability of the patent office, not on the basis that it takes time. If having pre-grant opposition results in a better patent system by weeding out non-patentable inventions the increase in time taken to grant a patent could be justified. If the time taken to dispose off opposition proceedings is one year and if it could be reduced with better working practices it is worth retaining this provision. As the patent term is twenty years and if patent examination takes 18 months and opposition proceedings another 12 months it will account for only about 13 per cent of the patent term.

There is a need to carefully consider the implications of substituting pre-grant opposition with post-grant opposition. Although many countries have adopted the system of post-grant opposition (the notable exceptions are Argentina and Thailand), the experiences of India and the US seem to suggest that there is a basis for continuing with pre-grant opposition. The Indian experience shows that between 1972 and 1987, about 7 per cent of the complete specifications accepted were denied patents because of opposition proceedings (Rao [2002]). This is quite a large proportion. If there were no pre-grant opposition proceedings these complete specifications accepted would have been granted patents. In the US, the quality of patents has seriously been affected because of the inability of the US Patent and Trademark Office (USPTO) to effectively examine the patents because of the mismatch between the resources available with the USPTO and the number of applications the patent granting office has had to handle in recent years.[6] This deluge of patent applications in the US, it may be argued is because the USPTO works on the assumption that "once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise".[7] A system that allows pre-grant opposition, on the other hand, may result in putting a check on the number of patent applications. Applications that contain claims, which are of questionable nature, may not be made in the first place. As was indicated earlier, a view that is generally held in the US is that patent applications are made only for the patent rights to be granted, and this view seems to have been strengthened by the fact that there are no pre-grant opposition proceedings.

Concluding Remarks

The ordinance that has been brought for the critical third amendment of the Patents Act 1970, has a number of issues that

would need close consideration before it is finalized. Recent experiences have shown that the patent system could indeed have an impact on access and affordability of medicines and it was therefore argued in the paper that the post-TRIPs patent regime that India is putting in place should address this area of concern. Appropriate provisions in respect of patentable subject matter, opposition to the grant of patents and granting of compulsory licences would, in our view, take care of some of the above-mentioned concerns. We would argue that the suggestions that we have made would go some distance in helping reach a balance between the rights and obligations of the patent holder – which is the primary objective of the TRIPS Agreement.

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2. National Institute for Health Care Management (2002), *Changing Patterns of Pharmaceutical Innovation: A Research Report*, May.
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NOTES

[1] We will refer to the Patents Act 1970 as the 1970 Act and the Patents (Amendment) Act 2002 as 2002 amendment.

[2] Article 65 of the TRIPs Agreement gave developing countries a period of five years from the establishment of the WTO to amend their patent laws. However, developing countries having a process patent regime were given a further period of five years to introduce product patents in the areas that were covered by process patents in the pre-TRIPs phase.

[3] In case of aspirin patent bearing the title, "Rapidly soluble aspirin compositions and method" (Pat No. 5,157,030) was granted in 1992, while "Stabilized aspirin compositions and method of preparation for oral and topical use" (Pat No. 6,248,731) was granted in 2001 and was renewed in 2004. In case of ibuprofen, patent bearing the title "Ibuprofen composition" (Pat No. 6,627,214) was granted in 2003.

[4] National Institute for Health Care Management (2002), p. 16.

[5] In some cases, Federal Courts in the US have ruled against companies which had tried to issue "new use" patents ostensibly for extending the lives of patents that were expiring and to block entry of generic manufacturers. Two of the better known cases involve Eli Lilly, which tried to prevent the marketing of the generic version of the popular antidepressant drug, Prozac, and Bristol-Meyers, which tried to block the entry of generic manufacturers by getting an additional patent on its anxiety treatment, BuSpar.

[6] In the US, there are 3,000 patent examiners who are called upon to examine applications totaling approximately 300,000 every year, for details see, FTC (2003), p. 12.

[7] FTC (2003), p. 12.

[8] The rights granted to patent holder under TRIPs Agreement are aimed at preventing third parties from making, using, offering for sale, selling, or importing the patented product or the product produced by using a patented process.

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NEWS
(NATIONAL/INTERNATIONAL)

Global Cos. File for One Million Patents

US Dominates Applications with Japan Following, and Germany Close on Their Heels

COMPANIES around the world have filed applications for 1 million international patents since the system began in 1978, the UN agency for intellectual property has said.

The US currently dominates the applications, filing 205,286 applications since 2000, said Samar Shamoon, spokeswoman for the World Intellectual Property Organization (WIPO).

Japan is in second place with 72,891, followed by Germany with 70,513, Britain 25,916 and France 24,278. "The US has consistently dominated," said Shamoon. But Japan has been catching up, overtaking Germany two years ago.

Shamoon said WIPO had separate statistics for individual corporations, with the Dutch manufacturer Philips Electronics NV leading the way with 9,778 applications filed between 1995 and 2003, the latest figures available. Siemens AG of Germany is in second place with 8,981, followed by Robert Bosch GmbH with 6,069 and Procter & Gamble Co of the US with 5,841 and Telefon AB LM Ericsson of Sweden with 5,072.

For a flat fee of 1,400 Swiss francs ($1,100) companies can file a request for patent protection in any or all of the 124 countries that have signed up to the system. WIPO registers the applications, publishes them and carries out an examination to determine whether the product or process in the application appears to be new. "The alternative is for you to go to every country individually and apply there for patent protection," Shamoon said.

By sector, the most patents are filed in pharmaceuticals (6%), followed by information technologies (5-6%), and biotechnology (3%).

(*The Economic Times*, 16 January 2005)

India Inc Files for 1,700 Patents

THE mailbox mystery is clearing up gradually, unveiling different contours of the product patents regime that came into place in the new year. India Inc has placed 1,700 applications in the patent mailbox while the total number of applications is around 9,000. According to the Government estimates, 7,000 of the applications are for pharma products and a majority of the multinational applicants are US companies.

According to Ashok Jha, Secretary in the Department of Industrial Policy & Promotion, only 2,500 of the 9,000 applications are being pursued. In other words, the other 6,500 are lying dormant while examination requests have been submitted in the case of these 2,500. The number of molecules that are available for patenting is estimated to be around 200. The average number of inventions in the post-1995 period works out to nearly 20 per annum, Shri Jha said.

The average time required for processing patent applications is estimated at two to four years, he added. Therefore, there is no question of any immediate impact of the new regime in terms of disruption in production and sale of generic drugs. "We have included adequate safeguards to prevent any rise in prices of essential drugs while patents can be denied due to 15 types of reasons. If adequate quantity of a particular medicine is not available at reasonable prices, the Government can intervene," Shri Jha said. Apart from the safeguards under the patents law, the drugs would be also subject to the Drug Price Control Order, which is compatible with WTO rules, he added.

Pre-grant opposition can be filed within 30 months from the date of publication of the application concerned. Post-grant application can be filed by parties other than those involved in the pre-grant opposition. The time-bound nature of opposition is in view of past instances where opposition to patents have dragged on for 15 years in some cases. While discouraging frivolous opposition, all provisions have been made to provide due consideration to serious arguments against any patent.

(*The Economic Times*, 6 January 2005)

Day 1 of Product Patent Regime

Pharmaceutical Industry Kept Guessing

THE Indian patent office's mailbox facility is turning out to be the proverbial Pandora's box! It has kept the pharmaceutical industry guessing on how many patent applications have been filed in the 10-year period leading to the product patent regime that kicked-in this month.

Are there 7,000-odd applications, as the pharma companies were given to believe through their own intelligence sources? Or is it 12,000 applications, as mentioned recently by the Union Commerce Minister, Kamal Nath? Probe the Indian patent controller's office and a third figure emerged. About 10,000 applications would be a realistic figure, an official said.

Monday, 3 January, was the official day 1 under the product patent regime for the Patent Controller General of India in Mumbai and its associated offices in Chennai, Kolkata and Delhi. And opening the mailbox is one of the main tasks that the patents office is faced with.

The mailbox provision is a facility that the Government put in place for the transitory period from 1995 to 2005. Drug firms interested in getting a 20-year exclusivity or patents on the sales of their medicines were asked to mail in their applications, which were to be opened up from January 2005.

But the lack of clarity on the final number of product patent applications in the box has left the domestic drug industry worried. By its own earlier estimates, the pharma industry had said that of the 7,000-odd applications in the mailbox, about 4,000 were related to pharmaceuticals and of this about one-quarter were applications filed by local companies.

The significance of an increased number of pharma-related applications for product patents is that more drugs would come under an exclusive umbrella, which would block local generic companies from making chemically-similar versions of the same drug. And this practice, domestic drug industry representatives apprehend, would increase the price of drugs.

Representatives with multinational drug companies (MNC) too fear the mailbox, but for different reasons. If a company gets a patent in August, for example, a generic company will not be prevented from making copies of that drug till that month. Worse, the innovator company (with the patent) will not be able to file for damages with retrospective effect either, laments an MNC official. So, if a patent gets delayed for some reason, generic companies will still be able to market the drug. This is a back-door entry for them, he points out. But a patent office official defends: no more back-door entries will take place. Applications will be cleared quickly and on a first to file basis, he said.

(*The Hindu Business Line*, 4 January 2005)

New Amendments to Patents Act, 1970 to Affect Farm Sector

THE new Ordinance, issued by the Government for amending the Patents Act, 1970, is likely to affect the farm sector as it extends the product patent regime to agro-chemicals, food and biotechnology products, apart from drugs and pharmaceuticals.

This is the third amendment to the patent law, in succession. This was done to fulfill the country's commitment to TRIPs and WTO. The amended patent law came into effect from 1 January 2005.

The new amendment has not categorically excluded seeds developed by novel means. Though India had earlier opted for the *sui generis* system for

protection of plant varieties and had subsequently put in place, the Plant Varieties Protection & Farmers' Right Act, lack of clarity in the amended patent law will lead to a situation of patenting of seeds developed by novel means, particularly the transgenic seeds.

The seed industry, engaged in developing transgenic seeds, is eager to seek such a protection, citing Article 27 of the TRIPs Agreement. The TRIPs Agreement has stipulated three criteria for patent rights, namely novelty, inventive step and utility.

Though the second amendment to the Patents Act had excluded plants from the patent regime, it said that the bio-technological processes, to develop unique plants, can be covered under patents. The third amendment, which has extended the product patent regime, has not categorically excluded such seeds from being patented. It has done little to restrict the scope of patentability.

Several experts like Dr K.V. Swaminathan, Chairman of Waterfalls Institute of Technology Transfer and B.K. Keayla, Convener, National Working Group on Patent Laws had earlier criticized the liberal ways in which patent rights are granted, citing minor changes as "innovation". They had suggested granting of patent rights over basic invention.

The third amendment has limited the scope of pre-grant opposition to patent rights to mere filing of representation before the controller of patents, while at the post-grant stage, objections can be filed before the board constituted for the purpose.

This amendment failed to define the emergency clause, where the Government can step in and intervene in public interest. It mentions only the national emergency and circumstances of extreme urgency, without stating specific emergencies, relating to health and environment.

The third amendment, though, has a clause for dealing with abuse of patent rights, it fell short in defining the terms for commercial use. Such terms for commercial use are in vogue in Argentina, China, UK and France.

Defining terms for commercial use is necessary to check monopolies and encourage competition and this finds mention in Article 31(b) of the TRIPs Agreement. The TRIPs Agreement has not defined micro-organisms and microbiological processes.

Here, the question is whether the micro-organisms, existing freely, are patentable or their mere isolation in pure form are patentable or human intervention, in establishing a level of novelty in the discovered micro-organism, is needed for patenting. The USPTO verdict of the case Diamond vs Chakraborty in 1980 establishes that human intervention, leading to a novelty in expression, can be patented.

It says: "the respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity having a distinctive name, character and use..... His discovery is not nature's handiwork, but his own..."

The next question is whether a product produced by a micro-organism, which is known, can be patentable or the process is patentable. In absence of clear definition of micro-organism and micro-biological process in the TRIPs Agreement, the country's policy-makers need to draw a distinctive line between the product of human intervention, leading to novelty and those freely occurring in nature.

In the absence of clarity in the third amendment, claims in gene patent applications may pertain to genes or partial DNA sequences, proteins encoded by these genes, vectors used for transfer of genes, genetically modified micro-organisms, cells, plants and animals and the process of developing a transgenic product.

These may lead to multiple rights owned by multiple actors, called patent thickets over a final product. Hence, there are problems of not only patent thickets, but also of royalty stacking and reach-through claims.

The food sector in India will also have to face new challenges in the new patent regime. Different processes and products will become patentable.

There is, therefore, a need to document all the traditional processes as well as products, with a view

to reducing the number of controversies over claims for patent rights.

(*The Financial Express*, 3 January 2005)

Patents Office to Dispose of Objections Speedily

THE Government has notified the Patent Rules 2003, laying down the procedure for pre- and post-grant opposition to patents, among other things. Significantly, the rules provide for the patents controller to issue a composite order rejecting/ accepting the pre-grant representation and, at the same time, granting or refusing the patent.

Anybody wanting to object to a patent before the grant will have to initiate the opposition proceedings in a period not exceeding three months from the date of publication of the patent application, or before the grant of the patent, whichever is later. The objection shall include a supportive statement and evidence and a request for hearing.

As per the procedure, on receipt of the pre-grant representation, the patents controller will give a notice to the patent applicant on refusal or incomplete specifications. The applicant can then file a statement and evidence supporting the application. The controller will then either refuse to grant the patent, or ask for more specifications.

As per the rules, "After considering representation and submission made during the hearing, the controller shall proceed further simultaneously, either rejecting the representation and granting patent or accepting the representation and refusing the grant of patent on that application, ordinarily within one month from completion of the above proceedings."

The procedures assume significance in the backdrop of concern expressed by domestic industry about their inability to block grant of a bad patent before its grant under the Patents Act, thanks to the third amendment effected through an ordinance recently.

Industry circles had argued that grant of a bad patent due to avoidance of pre-grant opposition would allow the patent-owner to enjoy undeserved monetary benefits, nullifying or recouping of which through a post-grant legal process would be largely impractical. Bad patents could also hamper legitimate business interests of the generic drugs industry.

An earlier draft by the NDA Government had proposed to substantially dilute the pre-grant opposition provision. The change brought about by the recent ordinance and the rules are that the pre-grant hearing has been retained. The controller will have the discretion to go ahead with grant of the patent after considering the representation and submissions during the hearing. The Government's justification for this power to the controller is that in its absence, grant of patents could get thwarted or unduly delayed.

(*The Financial Express*, 1 January 2005)

Patent Law May Shake Up Domestic Drug Industry

INDIA'S drug industry enters a new era in 2005 when laws recognizing foreign patents take effect, ending a copycat trade that has fostered local pharma firms for three decades and helped bring cheaper medicines to the poor. By presidential decree recently, India met a World Trade Organization (WTO) commitment to recognize foreign patents from 1 Jan., the culmination of a 10-year process. The change will become law if ratified by Parliament at its next session in February 2005.

India has allowed its pharmaceutical makers to copy drugs patented abroad since the early 1970s, as long as they used different manufacturing processes. The allowance helped a few such as Ranbaxy Laboratories Ltd., grow into global challengers and made medications cheaper for the poorer masses who often need them most. Multinationals such as GlaxoSmithKline Plc, Pfizer Inc., Novartis AG and Aventis, who have been forced to watch Indian firms eat into their market share, await the new environment with cautious optimism.

"It is certainly a milestone that product patents will be recognized in India," said S. Ramkrishna, Senior Director, corporate affairs at Pfizer India. "There is already a mindset change in the industry in India and also the global industry's perception of India."

"This will definitely encourage multinationals to invest in India, provided the product patent law is implemented and policed well," said Ranjit Shahani, President of the Organization of Pharmaceutical Producers of India and the head of Novartis India. The new rules do not apply to drugs patented before 1995, so Cipla Ltd. can continue selling its widely distributed version of the HIV treatment AZT. Even copies of drugs patented between 1995 and the introduction of the law are unlikely to be withdrawn.

Nor are foreign companies expected to introduce a flood of new products they have so far kept off the Indian market. Most are still grappling with the nitty-gritty of the proposed law and fear that questions about what is or isn't patentable will ultimately be answered in the courts.

"There is unlikely to be a steep change in the market dynamics immediately after the introduction of product patents," said a GlaxoSmithKline Pharmaceuticals Ltd. spokesman.

Still, big pharma firms see India as a lucrative new market. "There could easily be 70 to 80 million people who can afford expensive medicines, just as they go out and buy expensive cars, branded clothes and consumer goods," said an executive at one drug manufacturer. "That is equal to the size of a UK or a Germany."

The Government and foreign companies say medicine prices are unlikely to shoot up, because 95 per cent of the drugs sold in India are older molecules. Supply of generic drugs would continue and be adequate to treat most needs. Last year, more than 60,000 generic brands in 60 therapeutic areas were available in India, which accounts for 1 per cent of the value and 8 per cent of the volume of the world pharma market.

(*The Financial Express*, 1 January 2005)

Post-Product Patent, R&D is Way Forward for Pharma Cos

WITH the Government putting in place a product patent regime from 1 January 2005, domestic pharmaceutical companies are focusing their research and development (R&D) efforts on various therapeutic segments ranging from metabolic disorders, diabetes, pain management, anti-infectives and even cancer.

Malvinder Mohan Singh, President (Pharmaceuticals), Ranbaxy Laboratories, said that his company's focus on R&D is evident from the fact about 150 new scientists have been added to their team, including 30 expatriates. The company is bracing for opportunities in the US and European markets when several drugs are expected to go off-patent in the next few years. "We will be focusing on development of new drug delivery system (NDDS) as well as new chemical entity (NCE)," he said.

An official of Wockhardt Ltd said, "We saw the writing on the wall much earlier and spent close to 7 per cent of our revenue on R&D." Added J.P. Parswani, Vice-President, Marketing, Cadila Pharmaceuticals, "While we are focusing on both developing new molecules and new delivery systems, our aim is to reduce patient suffering and bring the cost of drugs down."

An ICRA study also points to R&D being a key focus area. It says, "Quite a few Indian companies have increased their focus on discovery of NCE and have progressed to the stage of clinical research; this has been achieved at a fraction of the international costs."

For example, Ranbaxy Laboratories Ltd's molecule for pulmonary asthma is in the second phase of clinical trials and another molecule for malaria in the first phase. Dr Reddy's Laboratories Ltd has two anti-cancer drugs in Phase I and Phase II stages and a dyslipidemia drug in Phase I trial stage. The company has four other molecules in pre-clinical trial stages.

Cadila Pharmaceuticals has five molecules for metabolic disorders and pain management in pre-clinical trials, Wockhardt has an anti-infective which has completed Phase I trial in India while Lupin Ltd's anti-migraine is in Phase II trials, anti-psoriosis molecule is undergoing Phase I trials and anti-TB molecule is in the pre-clinical stage.

While stating that increased R&D throws up various opportunities, on a cautious note, the ICRA report has said, "The next stages, viz. Phase II and Phase III clinical trials involve major expenditure and

may be beyond the financial capabilities of most Indian companies."

Indian companies have limited experience in conducting extensive clinical trials, which spans across the globe, and in interacting with international regulatory authorities during the process of approval of NCE.

(*The Hindu Business Line*, 1 January 2005)

Patent Ordinance Eases Processing, Removes Exclusive Marketing Rights

THE patents ordinance promulgated by the Government of India on 26 December for the third amendment to the Patents Act introduced product patenting in pharma, food and chemicals effective from 1 January rationalized and reduced the timeline for processing patent applications and did away with the transitional provision of exclusive marketing rights.

The ordinance, meant to meet the Trade Related Intellectual Property Rights (TRIPs) deadline for introduction of product patents in the three sectors, did not differ much from the bill introduced in the previous Lok Sabha by the NDA government. The "improvements" upon that bill which the ordinance brings are:

- Software would now be patentable if embedded with hardware. Currently, the intellectual property rights (IPRs) protection with regard to software are limited to copyrights.
- The rights of mailbox applicants have now been rendered "prospectively operational only," that is, only from the date of grant of the patent and not retrospectively from the date of publication. Mailbox is a facility introduced in the Patents Act through the first amendment in 1999, allowing anybody to apply for patents for inventions made during 1995-2005. The new provision also gives existing generic producers of likely-to-be-patented drugs protection from patent infringement suits. Processing of the mailbox applications - there are already over 12,000 of them – can start from 1 January.
- The ordinance seeks to retain a definite, time-bound (90 days) pre-grant opposition provision, which the earlier draft sought to dilute with a weak, pre-grant representation. However, the opposition would now be allowed only on the grounds of "patentability." Post-grant, a patent can be opposed before the patents controller as well as in a court of law.
- Indians wanting to file for patents abroad will need a no objection certificate from the Indian Government. This provision has been included specifically to guard against patenting of dual use technologies, one of which could be hazardous.
- Compulsory licence - which is a facility with the Government to sidestep patents under defined circumstances - can now be issued "without the grace period of three years from grant of patent."

These apart, the ordinance is learnt to have kept a provision to the effect that the Government would be able to use the compulsory licensing facility, if the patent-holder "works" the patent by mere imports.

Significantly, no change has been made in chapter 16 of the Patents Act dealing with compulsory licensing (excepting a complementary licence for exports under para 6 of Doha declaration to countries with no or insufficient production capacities in pharma sector). No change has been proposed in the criteria of "patentability" also.

Defending the amendment as a momentous step to enhance India's stature as a credible participant in the multilateral framework under the WTO, Commerce and Industry Minister Kamal Nath told mediapersons on 27 December, "The law effectively balances and calibrates IPR protection with public health concerns and national security."

He added, "India's pharma and biotech industries would benefit from patent protection. Pharma exports are set to double from Rs 14,000 crore at present in three years." The Minister pitted the legislation against the phase-out of Multi-Fibre Arrangement (MFA) in textiles. The 13 provisions of compulsory licensing coupled with the facility for outright acquisition of patents to cope with national emergencies are sufficient safeguards, he said.

Responding to the fears of drug prices going up in the product patent regime, the Minister pointed out that 97 per cent of all drugs manufactured (in the world) are off-patent, including all life-saving drugs. Overnight the situation would not change, even when a drug is patented, availability and affordability of the relevant treatment is not always in question for that very reason, as therapeutic alternatives to that drug would be available in the generic domain. Price control is in-bulit in the Act, he said, alluding to the Government's power for invoking compulsory licence if the patented invention is not available for public at a "reasonably affordable price."

"We have kept provisions to the effect that mere importation would not suffice to "work" a patent in India, the Minister said, indicating that such non-working could lead to use of the compulsory licensing facility.

Terming the promulgation of the ordinance as an "interim measure," the Minister said the Parliament will discuss it in detail in the budget session. He, rather incogently, ascribed the Government's failure to have the legislation passed by the Parliament before the TRIPs-mandated deadline of 1 January 2005, to "some politcal parties" giving their comments as late as 21 December.

The timelines for processing of applications have been rationalized so as not leave everything open-ended. This reduces by half the maximum time for processing of an application from more than nine years to about four years, the Minister said.

(*The Financial Express*, 28 December 2004)

Patents Extended to Pharma, Chemicals & Food

THE Government has met the 31 December deadline for complying with its commitment to the World Trade Organization (WTO) on patent law by promulgating an ordinance to extend product patents to pharma, food and chemicals.

Rules for operation of product patents would be notified soon on the basis of the ordinance. The Government now plans to introduce the third amendment to the Patents Act in Parliament during the forthcoming budget session. The amendment Bill needs to be cleared by Parliament within seven weeks from the time the budget session begins.

The Commerce & Industry Minister Kamal Nath said patents would be granted only prospectively and the protection will be valid for 20 years from the date of application. Producers of generic drugs can continue to sell them till the innovator gets a patent, he added. The ordinance is also a provision to grant compulsory licence to an Indian company to make and export a drug under patent to countries with insufficient or no manufacturing capacity to meet a public health crisis. This provision is in accordance with the Doha Declaration on public health.

Shri Kamal Nath said the Government has the power to revoke a patent, which is found to be mischievous to the state or prejudicial to the public. Also, compulsory licences would be issued to a local drug firm to make a patented drug if the patented invention is not available for public at "reasonably affordable price and if the patent is not worked in the territory of India".

The Government has reserved the right to issue compulsory licences under certain conditions during the three-year grace period from grant of patent. The Government also has the power to acquire a patent to meet a national requirement.

The Ordinance also facilitates production and marketing of patented products immediately after expiry of a patent by permitting preparatory action by non-patentees during the life of a patent.

Also, parallel import to make a drug available at the lowest international price has been allowed, Shri Kamal Nath said. Imports alone will not suffice working of a patent, the Minister said while indicating that local production would be mandatory. A number of safeguards have also been introduced to ensure public interest, he added.

Provisions related to processing of patents have been streamlined to cut down delays in issue of patents. Instead of the existing provisions that would take nearly eight years, the simplified procedures would ensure processing within four years.

Since the provisions related to exclusive marketing become redundant with the introduction

of product patents, those provisions have been deleted. Now patents would cover all fields of technology including pharma, food and chemicals, Shri Kamal Nath said.

"Fears of spiralling of drug prices were completely unfounded as 97 per cent of the drugs (sold in the Indian market) are off-patent," Shri Kamal Nath said. In the case of the 3 per cent drugs which can be patented, he added there were various alternatives available to the Government to ensure their availability at affordable prices.

(*The Economic Times*, 28 December 2004)

Embedded Software Gets Patent Protection

THE Government has decided to allow patent protection for embedded software. As of now, software applications embedded in hardware were provided only copyright protection.

The ordinance issued by the Government to comply with India's commitment to the WTO provide for award of patents to software embedded in hardware applications like mobile phones, TVs and computers.

Provisions relating to patenting of software-related inventions when they are in combination with hardware have been modified, Commerce & Industry Minister Kamal Nath said.

The facility is available for these inventions when they have technical applications to industry. The modification will help Indian industry, which is strong in software, to protect its intellectual property rights (IPRs), he said.

Nasscom has supported the idea of bringing embedded software under patents, the Minister said. Thereafter, consultations were held with various stakeholders. Various sectors of the Indian economy, including biotech and software, would benefit with the introduction of product patents, Shri Kamal Nath said.

A large number of patent applications are being submitted by Indian companies which are increasing their expenditure on research and development, he added.

(*The Economic Times*, 28 December 2004)

Pre-Grant Opposition to Patents Still Vague

THE pre-grant opposition rights provided in the patents amendment ordinance remains vague with no time-frame specified for a decision on such objections. Also, polimorphs or new forms of older drugs have not been specifically excluded from patenting.

Government sources said the decision on the opposition would come only when the patent application is granted or rejected. This, some section of the Government said, negates the use of such a provision by sealing the opportunity for seeking judicial review if the opposition has been unfairly rejected.

The Indian Drug Manufacturers Association (IDMA) expects the Government to specify a time-frame for a decision on pre-grant opposition in the patent rules which are to be notified soon.

The Union Commerce Minister Kamal Nath said that, after extensive discussions, the Government decided to allow both pre-grant and post-grant opposition. Sources within the Government, however, said the grounds for pre-grant opposition has been substantially cut to just two. No change in this regard has been made as compared to the earlier draft which was referred to the Group of Ministers (GoM) which looked into the proposed amendments in the patent law.

"The law as it exists today provides eight grounds for pre-grant opposition and this was reduced to two in the 2003 bill drafted by the previous NDA government. The current ordinance has not strengthened this provision, contrary to the claims made to that effect," said the source. "Mere new use" of an old molecule will not be eligible for patent under the current ordinance. In other words, the applicant has to show it qualifies the patentability criteria. However, the ordinance does not exclude a polimorph, hydrate or a metabolite from getting patented, points out Indian Pharmaceutical Alliance Secretary General D.G. Shah. The Government's stand is to let "jurisprudence develop on these issues" — a euphemism for not plugging scope for litigation, sources said.

(*The Economic Times*, 28 December 2004)

Mailbox to Come Alive as Product Patents Kick in

NEARLY 12,000 patent applications, a majority of them from multinational pharma companies, would be opened by the Government on 1 January as the Government has complied it with WTO obligations by issuing an ordinance to bring about product patents for chemicals, agrochemicals and food sectors.

Rules for operation of product patents would be notified soon on the basis of the ordinance. The applications are lying in the "mailbox"' provided by the Government for submission of applications in the run-up to the introduction of product patents.

The Commerce & Industry Minister Kamal Nath said that patents based on the mailbox applications would be awarded only with prospective effect. The patent will be available from the day of award and not the day of application. "We have specifically provided that patent rights for mailbox applications will only be available prospectively. We have made these changes after wide consultation, and we feel that these considerably improve the proposals," he said. Current estimates are that it will take up to 30 months to process these applications. The Government feels that all the applications would not be pursued and it will take a couple of years to award patents.

The new provision introduced to circumscribe rights in respect of mailbox applications to prospective effect will protect local manufacturers from unfair charges, said Shri Nath. Even if a local producer manufactures a product for which patent is granted, the liability will be limited to the period after the grant of the patent.

Once the mailbox is opened, the list will be published and all the stakeholders will get an opportunity to oppose any application. The Government will consider all aspects including opposition or objections — if any — before taking a final decision.

The Government has introduced a number of safeguards and prices of pharmaceuticals will not shoot up, Shri Kamal Nath said. Only 3 per cent of the drugs produced in India now are patented, the Minister added while defending the new patent regime. On the other hand, he claimed better options would be available as research & development would be encouraged by the new regime.

(*The Economic Times*, 28 December 2004)

Public Health Interest Fully Protected: Kamal Nath

Important Public Interest Provisions in the Patent Law

SHRI Kamal Nath, Union Minister of Commerce & Industry, has said that the Patents (Third) Amendment ensures that the reasonable requirements of the public with respect to availability and affordability are taken care of and public interest particularly public health and nutrition is protected. "The law effectively balances and calibrates Intellectual Property protection with public health concerns and national security. By participating in the international system of intellectual property protection, India unlocks for itself vast opportunities in both exports as well as its potential to become a global hub in the area of R&D based clinical research outsourcing, particularly in the area of bio-technology", he said.

The important public interest provisions in the Patent Law announced by Shri Kamal Nath, are:

(a) **Conditional grant of patent [Section 47]**: This empowers the Government to import, make or use any patent for its own purpose. For drugs, it also empowers import for public health distribution.

(b) **Revocation of patent in public interest [Section 66]**: This empowers the Government to revoke a patent where it is found to be mischievous to the State or prejudicial to the public.

(c) **Grant of compulsory licence [Sections 82 to 94]:** ***Chapter XVI*** deals with the general principles and circumstances for grant of compulsory licences in order to protect ***public interest*** particularly ***public health*** and ***nutrition***. These provisions check the abuse of patent rights. They can be invoked if the ***reasonable requirements of the public*** with respect to patented inventions

have not been satisfied, and the patented invention is ***not available*** for public at a ***reasonably affordable price,*** and if the patented invention is not worked in the territory of India.

Note: **[Section 92]:** This provides for action in case of ***national emergency, extreme urgency*** and ***public non-commercial use,*** and ***can be invoked without the grace period of 3 years from grant of patent.***

(d) **Use of invention for the purpose of Government [Sections 100 & 101]:** This complements Section 47.

(e) **Acquisition of invention and patent for public purpose [Section 102]:** This empowers the Government to acquire a patent to meet national requirements.

(f) **Bolar provision [Section 107(A)(a)]:** This facilitates production and marketing of patented products immediately after expiry of term of patent protection by permitting preparatory action by non-patentees during life of patent.

(h) **Parallel import [Section 107(A)(b)]:** This provides for import so that patented product can become available at the lowest international price.

The Minister said that the Ordinance on Patents was the same as the Bill introduced last year but with improvements in some significant respect. Elaborating, he said, "we have introduced a provision for patenting of software that is embedded in hardware. We have also provided for a definite pre-grant opposition procedure. The earlier bill had only a post-grant opposition, with a weak pre-grant representation. After extensive discussions we have decided to have both pre-grant as well as post-grant opposition. Of course, we have rationalized the timelines, so as not leave everything open-ended, but have a definite time-table within which each of the stages should take place. This reduces by half the maximum time it would take for the processing of an application, from more than nine years to about four. Another significant modification is the introduction of a provision to protect Indian industry from infringement proceedings with retrospective effect. We have specifically provided that patent rights for mailbox applications will only be available prospectively. We have made these changes after wide consultation, and we feel that these considerably improve the proposals". He further said that the Ordinance would be discussed in detail in Parliament in the Budget session.

Giving the background to the Ordinance, Shri Kamal Nath said that this Third Amendment was only the culmination of a process begun 10 years ago. The Bill was introduced in Parliament a year ago by the previous government, but it lapsed (owing to the

Salient Features of Third Amendment to the Patent Law

India Introduces Product Patent Regime

(a) Extension of product patent protection to all fields of technology (i.e., drugs, food and chemicals);

(b) Deletion of the provisions relating to Exclusive Marketing Rights (EMRs) (which would now become redundant), and introduction of a transitional provision for safeguarding EMRs already granted;

(c) Introduction of a provision for enabling grant of compulsory licence for export of medicines to countries which have insufficient or no manufacturing capacity, to meet emergent public health situations (in accordance with the Doha Declaration on TRIPs and Public Health);

(d) Modification in the provisions relating to opposition procedures with a view to streamlining the system by having both pre-grant and post-grant opposition in the Patent Office;

(e) Addition of a new proviso to circumscribe rights in respect of mailbox applications so that patent rights in respect of the mailbox shall be available only from the date of grant of patent, and not retrospectively from the date of publication.

(f) Strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies;

(g) Clarification of the provisions relating to patenting of software-related inventions when they have technical application to industry or are in combination with hardware;

(h) Rationalization of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent applications, and simplifying and rationalizing procedures.

elections). "The new government set up a group of Ministers on the matter. It was our desire to bring the Bill to Parliament first. But it was also necessary to consult with all stakeholders and political parties. The last comments we received were on the 21st of December – and so it was not possible to bring the Bill to this session of Parliament. This has necessitated the Ordinance. The ordinance will be discussed in detail in Parliament in the Budget session. The ordinance is an interim measure to fulfill our legal obligations within the stipulated time".

(*PIB Press Release*, 27 December 2004)

Concern Rises within Govt over Default on Patents Deadline

"Country's Credibility at Stake"

THE Ministry of Commerce and Industry, which is piloting the Patents (Third Amendment) Bill, has said that besides raising a question-mark over the country's credibility in the international arena, there could be "serious legal implications" if the laws are not made WTO compliant within the deadline.

In a comprehensive note on the issue, the Ministry has pointed out that the Government would have no legal basis to defend the default as the country had already exhausted the 10-year transition period provided to move from a process-patent regime to a product-patent regime. It further said that India could throw itself open for being dragged to the international legal forum by other WTO member countries. The non-compliance with the WTO commitment would directly impact the medicines or drugs industry, the food sector and other substances produced by chemical processes.

The note indicates that a major area of concern for the Government is the over 4,500 applications currently posted by various pharmaceutical companies in the mailbox facility. This could lead to a legal vacuum, as there is no clarity on whether the mailbox facility would continue to exist or cease to do so. Also, there would be uncertainty on how new patent applications would be treated after 1 January 2005.

Meanwhile, as the ambiguity surrounding the Ordinance on the Patents Bill continues, sources said that deletion of Section 5 of the Act would be the key. The deletion of this would enable the Patent Office to grant both process and product patents in all fields as per the TRIPs (Trade-Related Intellectual Property Rights) Agreement.

The Group of Ministers (GoM), constituted in August this year, had agreed to both pre and post-grant opposition hearing of patents. While a window of 90 days would be provided for companies to challenge patent applications is proposed before a patent is granted, post-grant opposition would be allowed any time during the lifetime of a patent. These safeguards are present in countries such as China, Brazil, Japan, Korea, US and the European Union.

Also, safeguards have been proposed to prevent evergreening of patents. Patents would be granted to inventions and not to discoveries, said sources.

The GoM has also been in favour of scrutinizing all the mailbox applications and has rejected the request by domestic companies seeking waiver from patent infringement. It felt that such a move would go against the TRIPs Agreement and would infringe the rights of the patentee. The GoM also felt that safeguards already exist to ensure the availability of drugs. In case of a national emergency, the Government could in public interest, go in for parallel imports and import medicines for distribution.

(*The Hindu Business Line*, 25 December 2004)

Govt Intensifies Efforts to Digitise Traditional Knowledge Base

THE Government may have left the Patents Amendment Bill hanging, but intensive efforts are on within the country to protect its very own traditional knowledge base from being misappropriated and patented abroad.

The National Institute of Science Communication and Information Resources (Niscair), a body under the Department of Science and Technology, has intensified efforts to convert about 23,000 new Ayurvedic medicine formulations and 77,000 Unani medicine formulations in a digitised format compatible with International Patent Classification.

"Converting the 23,000 Ayurvedic formulations into a digitised format should be completed by end-2005. The Unani formulations should be digitised by mid-2006. We would also soon start working on the knowledge of Yoga," according to the Niscair Director, V.K Gupta.

Niscair has already created a traditional knowledge digital library for 36,000 Ayurvedic medicine formulations. Shri Gupta said that protecting Indian knowledge pool would also involve making the information available in five international languages including English, Spanish, German, French and Japanese. The database would be made available in the public domain.

In the past, India had to fight cases in the international arena against misappropriation of its traditional knowledge by fighting patents claims related to medicinal use of *haldi* and *neem*.

A team of about 60-70 experts have been working on creating the digital library. "Besides experts in field of Ayurveda and Unani medicines, we have also started taking in doctors trained in modern medicine besides groups of patent and IT experts," Shri Gupta added. He said that Niscair has also decided to extend its expertise to help other countries protecting their traditional knowledge. "We are now going to help a few SAARC countries so that misappropriation of their traditional knowledge can be stopped," he added.

Many other countries including Singapore, Ghana, Egypt, Algeria and Uganda have expressed their interest in collaborating with Niscair for creating similar databases in their countries.

(*The Hindu Business Line*, 25 December 2004)

DRL & Ranbaxy Lead Race for Generics in US Market

INDIAN drug majors Ranbaxy and Dr Reddy's Lab (DRL), seem to have taken a firm grip of the $2-billion market for drugs going off-patent during 2005 and 2006. Ranbaxy and DRL have already bagged the largest number of US FDA approvals for these generic drugs, ahead of other global generic majors like Teva, Sandoz, Mayne and Bedford.

The cluster of blockbuster drugs going off-patent in 2005-06 are GSK's Paxil (paroxetine), Combivir (lamivudine), Retrovir (zidovudin) and Zofran (ondansetron), Merck's Zocor (simvastatin) and Proscar (finasteride), Pfizer's Zithromax (azithromycin), Abbott's Biaxin (clarithromycin), Schering Plough's Clarinex (desloratadine), Aventis' Amaryl (glimepiride), Novartis' Aredia (pamidronate) and Pharmacia's Fragmin (dalteparin).

Data available with *ET* from the companies and US FDA show that Ranbaxy and DRL till now have a relative advantage with a couple of 180 days exclusive marketing rights (EMR) as well. While both the companies have secured one final approval from US FDA for these generics, Ranbaxy has two tentative approvals and DRL one.

Israel's Teva, the world's largest generic drug company, with 90 per cent sales from US and Europe, has secured just one tentative approval till now. Novartis' generic arm Sandoz and US-based generic companies like Andrx Corporation, Barr Pharma, Bedford Lab and Mayne Lab have just one approval till now, with no tentative approvals.

Ranbaxy has already received the approval for clarithromycin along with Andrx and Roxane. It is also the only generic company till now to have received tentative approvals for Simvastatin and Pravastatin, whose patent expires in 2006. Quite naturally, the final approval for these products will be laced with the 180 days EMR period.

On the other hand, DRL has already secured the EMR for ondansetron. The company has also secured tentative approval for finasteride along with Teva. However, US FDA data point out that DRL has secured the tentative approval on 14 October 2004, earlier than Teva's on 26 October 2004. This paves way for DRL to secure another EMR.

(*The Economic Times*, 18 December 2004)

Will Generic Drugs from India Dry Up?

AS India enters the final-leg of its race to bring in the product patent regime, come January 2005, agencies working in health-related segments fear that

"a major source to generic medicines is likely to dry up".

And the concern peaked, with the increasing likelihood of the Government bringing in product patents through an Ordinance.

"We are concerned about what is going to happen in India as it would impact the access to medicines of not just the people in India, but also in other developing countries," said Ms Ellent Hoen with Medecins Sans Frontiers or the "Doctors without Borders". Newer medicines would become more expensive and the 20-year monopoly that a product-patent grants to a company would make it difficult to bring down the price of medicines, she said on a conference call with journalists across the world. Citing the example of anti-AIDS drugs, she said that the shift from the first line of treatment to the second line (involving newer drugs) would push up the patients' bill from $160 per person per year to about $4,000. In the past, generic or chemically equivalent AIDS drugs had played a pivotal role in forcing down prices in this segment.

There was no hurry, as we knew all along that the country was to go TRIPS-compliant by 2005. The Ordinance is worrisome as it would depend on what would be included. All we need is to bring in product patents for genuine products," said Anand Grover, Director with the Lawyers Collective HIV/AIDS Unit in India. But India is doing more than what is required as part of its international commitment, he said. "New usages or incremental developments on existing drugs should not be given patents. Other terms being used now are "near use" and such terms would only allow lawyers to make money by confusing the situation," he observed.

Ms Asia Russell, Director with the international advocacy group Health GAP, observes: "Approximately 67 per cent of India's generics are exported to poor countries, the impact of India's changes will be felt both domestically and in importing countries. Unless the Government of India takes action to prioritize the protection of public health, both for Indian consumers and consumers in importing countries, drug prices will rise and lack of access to treatment for public health problems will worsen."

(*The Hindu Business Line*, 17 December 2004)

Pharma MNCs in India in Consolidation Mode

BARELY two weeks to go for the product patent regime to come into force, multinational pharmaceutical firms are in the process of consolidating their Indian operations.

Two major pharma companies, Glaxo SmithKline and Sanofi Aventis, have already consolidated their Indian operations, while others are in the queue to follow suit.

According to industry insiders, the director board of Glaxo SmithKline Consumer Healthcare has recently finalized a Rs 123 crore buyback offer to enhance their stake in the company from 40 per cent to 47 per cent.

As per the director board's decision, the company, through the tender route, would buy back 33.25 lakh equity shares of Rs 10 each, accounting for 7.33 per cent of its paid-up equity capital, at a rate of Rs 370 per share. The tender route was preferred due to the thin trading volume in the stock.

Similarly, Sanofi Aventis is in the process of merging its Indian subsidiaries, Sanofi Lab and Aventis Pharma to consolidate its Indian operations. The French pharma giant would also enhance its stake in the merged entity to over 70 per cent.

The company has already got the go ahead from the authorities concerned and is expected to complete the process by the end of current fiscal. Sanofi Lab is a pure play marketing company while Aventis manufactures a range of products.

According to industry sources, the consolidation of Indian operations by multinationals is in view of the new product patent regime which would come into force from January next. The consolidation would bring synergy among different siblings of the pharma majors and would also give the advantages of an enhanced size.

"With a lot of generics currently manufactured by Indian companies expected to do a vanishing act from the pharma shelf and replaced by the original patented versions, consolidation would give companies a more focussed business strategy. It would also give them enough headway against

competition," industry insiders said, adding, "With almost all multinationals expected to either set up their facilities in India or start marketing their patented products, competition would become intense. Marketing costs for multinational drug companies are normally higher compared to local firms due to competition."

(*The Financial Express*, 16 December 2004)

Relief for Domestic Pharma Majors on Mailbox Filings

IN what could be a relief to domestic pharma majors, the Government has made a last-minute modification in the Patent Amendment Bill. Under this, beneficiaries of mailbox patent filings would not have the right to prosecute, with retrospective effect, producers of existing generic drugs on the grounds of patent infringement.

The Department of Industrial Policy and Promotion (DIPP) has sent a revised note on the Bill to the Cabinet, an official source said. If the Cabinet clears the Bill, it would be introduced in Parliament, or else, the Government may opt for the ordinance route to meet the TRIPs (Trade Related Intellectual Property Rights) deadline for introducing product patents in pharma and agrochem sectors.

The mailbox is a facility introduced through the first amendment to the Patents Act in 1999. It allows filing of applications for product patents for drugs, agro-chemicals and food products discovered during the period January 1995 - December 2004. The patent office will begin examining these applications from January, and any patent based on the mailbox filings, if granted, will be effective for 20 years from the date of mailbox application.

For instance, an application filed in the mailbox in 2000 can potentially lead to a patent valid until 2020. Domestic drug companies which already sell generic versions of the clutch of drugs for which mailbox applications are pending, feared they would then become liable for prosecution by successful mailbox applicants.

In future, it will be up to patent-holders and generic drug producers to sort the issue out either through commercial agreements or through litigation.

The revised Cabinet note does not propose any modification of provisions regarding "patentable subject matter" and compulsory licensing. This seems to be because they were framed as per the recommendations of the Joint Parliamentary Committee, which discussed the relevant issues in great detail.

The revised Bill also retains the provision for pre-grant opposition on grounds of patentability, the sources said. "All the points raised by the Left Parties have been addressed to the extent they can be," an official said.

(*The Financial Express*, 15 December 2004)

Pandora's Box Set to Open for Drug Majors

THE opening of the mailbox of patent applications in January 2005 will force a shakeout in the domestic pharma market. It will lead to withdrawal of certain branded generic versions of a clutch of drugs that may get patented in the exercise. Under the Patents Act, all patent applications for drugs discovered in 1995-2005 are to be deposited in the mailbox.

Domestic pharma firms, Nicholas Piramal India Ltd (NPIL) and Cadila Pharma that sell generic versions of cholesterol lowering drug rosuvastatin in the domestic market - branded Fortius and Rovalip respectively - will have to withdraw their products from the market, if Astra Zeneca, the inventor of the drug, receives the patent for its drug Crestor.

Sun Pharma and Intas may have to stop marketing new generation anti-epileptic drug gabapentin a few months from now. In the mailbox of patent applications with the Patent Controller of India, there are nine patent applications pertaining to the drug filed by Pfizer, the inventor of the relevant new chemical entity (NCE). Pfizer already holds the product patent for gabapentin (Neurontin) in the US. It will be valid until November 2008. In India, if granted, it will be valid even beyond the US patent's tenure. Cipla could be forced to recall its asthma drug formoteral fumarate (Forateo), since Novartis has a mailbox application for the drug's patent.

There are conflicting opinions on the status of mailbox applications. While the Indian drug companies perceive the threat to be grave, with a Rs 3,000 crore market slated to be destroyed gradually over a few months from January, multinationals say there are in fact only half-a-dozen such drugs, with a generic market size of about Rs 150 crore.

Data gathered by *FE*, however, show that at least 30 mailbox patent applications pose a threat to existing generic drugs. Patents have been sought for drugs such as amolidipine besylate/maleate (Pfizer), aripiprazole (Otsuka), ezetimibe (Scherring), losartan (Merck), cetrizine (UCB). Generic variants of all these drugs are in the market.

Officials from a leading MNC sought to dilute the perception that patents would destroy a large number of high value generics, saying that there are existing therapeutic equivalents for these products in the market. "Many patent applications do not lead to launch of commercially marketable products. Some of the mailbox applications may be for formulations that will not affect the domestic manufactures of the base molecule."

For instance, of the total systemic pain management market of Rs 1,250 crore, Cox inhibitors account for 19 per cent. And within the Cox inhibitors, Valdecoxib accounts for 46 per cent, with a total moving annual total (MAT) turnover of Rs 110 crore, as per the IMS figures of May '04.

"We have analyzed all products launched in the US post-1995 and examined whether they could qualify for patent protection in India. Currently, only six molecules have been introduced in India which could displace existing generics," said an official from another pharma MNC.

This period would have seen invention of roughly 135 NCEs in the world. Patents for all these 135-odd NCEs have not been filed for in India. For example, it is believed that Pharmacia (now merged with Pfizer) did not file for patent on Cox inhibitor Valdecoxib (Bextra) within the prescribed time. This, however, could not be independently confirmed. Significantly, as many as 36 generic versions of Valdecoxib are curently being marketed in India, with combined MAT of Rs 110 crore.

Similarly, Boehringer Ingelheim failed to make a patent application in India for its drug tiotropium bromide (Spiriva) for which the company has a European patent value until 2015. Roche did not file for patent on torsemide (Demadex) even as its US patent for the NCE will expire in 2007. So, the grantable product patents on drugs whose generic variants have already been introduced could not be more than 30.

Indian companies already marketing generic versions of the likely-to-be-patented drugs propose to pay royalty (4% of sales) to the patent holder, to compensate for their continued existence in the market after grant of patent. The generic drug producers say that they could not be held liable for patent infringement as they did not have prior knowledge of the patent application filed by the MNC.

The Group of Ministers, however, dismissed the proposal made by manufacturers of generic drugs. The GOM held that TRIPs' transition norms would not allow generic drugs to co-exist with patented drugs, unless there was a situation warranting invocation of compulsory licence.

(*www.financialexpress.com*, 6 December 2004)

Prevent Patenting of "Trivial Changes" Drug Cos. Tell FM

EVEN as the Government is attempting to resist Left parties' pressure for re-defining the patentability criteria in the patent bill, set to be introduced in the winter session of Parliament, a war of words has erupted in the pharmaceutical industry over the issue. The Indian Pharmaceutical Alliance (IPA), a grouping of 11 top notch domestic drug companies, has shot off a letter to Finance Minister P. Chidambaram seeking his support to preclude various new "forms" of already patented molecules (new chemical entities) from patenting.

According to IPA, allowing patenting of these forms – which, it says, represent "trivial changes," hardly distinguishing substances that are "essentially similar" – would tantamount to doing much more than what is obligated under the TRIPs. Such patenting regime, the IPA says, would seriously

constrain India's potential to capture one-third of the global generics market by 2010 with exports of over Rs 90,000 crore, as against current exports of Rs 15,000 crore.

Multinationals, however, have put up a strong defence, by quoting the details of the over 4,200 Patent Cooperation Treaty (PCT) applications filed by Indian companies like Ranbaxy, Cipla and Wockhardt for such "forms". They say if these are trivial inventions, unworthy of patenting, why have the Indian companies made these PCT filings. Bulk of India's drug exports are that of generics to lucrative US and EU markets, where strong patent regimes exist. India's adoption of a broader patenting policy would not alter the dynamics of drug industry's global market presence, the MNCs argue.

In the letter to Shri Chidambaram, H.F. Khorakiwala, chairman of domestic drug major Wockhardt, and president, IPA, annexed numerous examples of recurrent patenting of pharmaceutical substances that are "essentially similar" for "trivial changes."

Quoting the European Parliament's opinion, IPA president said that "different salts, esters, ether, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy."

To counter this, MNCs gave *FE* data saying the out of the over 4,200 PCT applications by Indian companies, about 55 per cent are for "incremental pharmaceutical inventions," which might fall in the category of trivial modifications, going by the Indian companies' argument.

Ranbaxy has as many as 239 PCT applications, of which 122 are for derivatives, compositions, formulations or dosage forms of an already patented NCE, while the rest are process patent filings.

Cipla, a robust generic company at variance with the concept of patenting, has 49 PCT applications, with 23 of them for incremental inventions. Wockhardt, which has a preliminary exposure to NCE research, has 35 PCT filings, 18 for incremental inventions.

To quote an instance, Ranbaxy has sought patent for nasally administrable bioavailable pharmaceutical composition of anti-allergic NCE Loratadine, whose patent is set to expire in 2024, says S. Ramakrishna, senior director, Pfizer India, "About 90 per cent of India's pharma exports are that of generics, to the lucrative US and EU markets. Export of patented drugs are very limited, and mostly to Sub-Saharan countries. A wider definition of patentability, compliant with the TRIPs, therefore, does not pose any threat to India's exports." Around 60 per cent of Ranbaxy's revenues are from exports of generics to the US.

However, according to Shri Khorakiwala, there are two types of intellectual property laws in the world – the "TRIPs-plus regime" of the US, EU and Japan and those imposed on some developing countries through bilateral pressures. Acknowledging that India is among very few number of countries that have taken advantage of the full extent of the TRIPs transition arrangements, without going overboard to be TRIPs-plus, he said: "No other country in the world has such a developed indigenous (pharmaceutical) industry as India… (India) has to demonstrate to the world that by bringing a TRIPs compliant regime, not TRIPs plus, it can restore balance between the interests of the innovator and the customer."

Currently, as per the criteria of patentability in the Patents Act, a patentable invention must be something new, involving an inventive step and capable of industrial application. However, these terms are not deconstructed further to state whether the "incremental inventions" are patentable.

(*The Financial Express*, 30 November 2004)

Tech Giants Edgy Over Patent Sale of Web Services

THE upcoming auction of dozens of key web services patents in a California bankruptcy case has some big Silicon Valley companies on edge.

Among them are Google, Oracle and Sun Microsystems. Attorneys for those and more than a dozen other companies held a pow-wow to discuss the patent sale and the danger of becoming targets of infringement suits by whomever acquires them.

They also discussed pooling their funds and jointly bidding in the Dec. 6 auction. A non-profit group called CommerceNet, which organized the meeting, offered to collect contributions and manage the bidding. If the joint bid won, CommerceNet would essentially retire the patents.

If it lost, CommerceNet would refund each contributor.

"It's a little bit like paying the blackmailer before they have something to blackmail you about," said Craig Smith, CommerceNet's chief financial officer and chief operating officer.

On the auction block are 39 patents held by Commerce One, a bankrupt software company in Santa Clara, California, that's in the process of shutting down and liquidating its assets. The patents cover technical protocols that underlie popular methods for exchanging business documents over the Internet.

The protocols, also known as Web services, are in wide use today. Microsoft, IBM and, presumably, the companies at this meeting have incorporated them into their software products and their own business systems, Mr. Smith said. Although it may turn out that the patents are too broad to enforce or may be otherwise invalidated if challenged, people are nervous.

"There's a concern that these patents could be used aggressively by a buyer to shake down the whole Web services industry," said Jason Schultz, an attorney at technology activist organization the Electronic Frontier Foundation. Mr. Schultz is helping put together and promote the CommerceNet proposal.

Alarm is growing within the high-tech industry over that some say is a trend towards speculative patent acquisitions. Critics say companies that acquire patent rights to technology that they played no role in creating in order to profit from infringement suits are violating the spirit of patent law, which is supposed to reward innovative companies. A number of companies specialize in this practice, including Intellectual Ventures, started by former Microsoft executive Nathan Myhrvold.

The CommerceNet proposal is a novel idea for dealing with the problem, EFF's Mr. Schultz said.

"It's like buying up nuclear material so it doesn't fall into the wrong hands," Mr. Schultz said. "It may be a new way to think about dangerous patents," he continued. "We may see it replicated, especially in bankruptcy cases."

CommerceNet, which is based in Mountain View, California, is seeking initial contributions of up to $2 million each from five to 10 companies. But it doesn't have much time. The auction is scheduled for Dec. 6 in federal bankruptcy court in San Francisco, and bidders must submit initial offers by Dec. 2 to participate. CommereceNet may request that the court postpone the auction.

So far, no one has stepped forward to pledge a contribution to the CommerceNet effort, Mr. Smith said. Representatives for Google, Oracle and Sun refused to comment on the CommerceNet meeting and their plans regarding the auction. Microsoft and IBM representatives did not immediately respond to questions about the auction.

The patents could fetch more than $10 million and bidding is set to start at $1 million.

A buyer looking for a lucrative profit on the deal may seek anywhere from $100 million to $1 billion in royalties or settlements and is likely to target companies with deep pockets, such as Microsoft and IBM, said Van Pelt, who is also involved in organizing the CommerceNet proposal.

(*The Financial Express*, 29 November 2004)

Amendments to Patents Law on Course

THE Group of Ministers (GoM) on patents has finalized its recommendations for undertaking amendments to the Patents Act. The amendment Bill is expected to be introduced in the winter session of Parliament.

"Both pre and post-grant opposition facility will be there, but the provision will be made in a way that the whole purpose of the law is not defeated," Commerce and Industry Minister Kamal Nath said after a meeting of the GoM.

The issue of including a provision to contest a patent, which has already been granted, had been one of the contentious issues with the domestic

pharmaceuticals industry. The scrapping of the pre-grant objection provision in the Patent Amendment Bill 2003, caused a lot of heartburn among the domestic pharma companies, which were of the opinion that it would lead to the grant of frivolous patents. Sources said the GoM had decided that an opposition to the grant of a patent would not hold up the processing of the patent application. The Government will adhere to the 1 January 2005 deadline for the product patent regime, he said. A modified Bill, incorporating the decisions of the GoM, would now go to the Union Cabinet.

The Government officials said that the amendments being proposed, have incorporated the concerns of all other departments, including security concerns and issues pertaining to patentability of embedded software in hardware.

(*Business Standard*, 26 October 2004)

Big Pharma in Consultation with the Government

A few weeks ago, multinational Roche's head of pharmaceutical business — William Burns — came to India on a whistle-stop tour. His itinerary included a visit to New Delhi where he met Kamal Nath, the Union Minister of Commerce & Industry. Mr Burns is not the only top big pharma official to have called on various ministries. Over the last few months, there has been a steady stream of visitors — top officials of multinationals and Indian companies alike — to meet ministers and the top bureaucracy.

The increasing interest is understandable. Currently, a team of ministers and bureaucrats are putting finishing touches to a document which will ultimately pave the way for a new Patents Act. This document — the third amendment to the patent bill — is to be tabled in the winter session of Parliament.

Because of the implications that this new Act will have, there are many groups that want their viewpoints represented in the Act. "There is a lot of resources and pressure being used to influence the new policy," says an industry observer.

To understand why, one needs to go back a couple of decades. In 1970, a new patent law was passed, which came into effect in 1972. This was a watershed in the history of the Indian pharmaceutical industry.

The Patent Act of 1970, which only acknowledged process patents and not product patents, was instrumental in providing the domestic players an impetus to grow and emerge as strong producers of formulations and bulk actives. However, the Act simultaneously thwarted global pharma companies' plans and hence there was no interest for international companies to file pharma patent applications in India. But now, the wheels are about to turn full circle. With India being a signatory to the WTO, the country has to enact a new patent law by 1 January 2005 to fulfil its Trade-Related (Aspects of) Intellectual Property Rights (TRIPs) obligations.While India has to have a new patent law, TRIPs provides for some amount of flexibility as to when the new law has to come into force. The Act of 1970 has already gone through two amendments in the process of creating a new Act. Now as the third and final amendment is being put together, there are some contentious issues that have yet to be resolved. To begin with, different industry bodies have disparate ideas on what constitutes a patentable invention. The Indian Drug Manufacturers' Association (IDMA) and the Indian Pharmaceutical Alliance (IPA) in their memorandum to the Ministry have demanded a tighter definition of the criteria for patentability.

IPA does not want new forms of previously patented compounds — like salts, isomers and polymorphs, among others — to be patentable. The IDMA also has a similar view, stating that product patents should be granted only to new chemical entities (NCEs). "We do not want the policy to be loosely worded as this would provide a loophole to extend life of patents," says D.G. Shah, Secretary General of IPA. TRIPs provides for patent protection of 20 years. However, pharmaceutical companies in other countries have exploited loopholes in the law leading to patents being extended.

The Organization of Pharmaceutical Producers of India (OPPI) and the Corporate Law Group, which represents PhRMA (a US-based pharmaceutical industry group) in India, do not want the patentability criteria to be limited to NCEs alone.

"Incremental innovation, if patentable, is the low hanging fruit that Indian industry could take advantage of," says a senior official with a pharma MNC. OPPI would also like new uses of a known molecule to be patentable. Another controversial aspect involves Section 25, which details the mechanism to oppose a patent. As it stands, this section provides for pre-grant opposition. But the current version of the amended bill proposes to remove this and provide for only post-grant challenge, which has not gone down well with the domestic industry.

(*The Economic Times*, 21 October 2004)

Patently Yours, NDA Assures Govt

IN a major relief for the Government, the NDA has promised to back the Patents (Third Amendment) Bill. The Government, which gave up its plans to opt for the ordinance route, will bring the bill in the winter session of Parliament.

With the TRIPs Agreement on protecting product patents in all fields of technology scheduled to come into force in the country on 1 January 2005 it has become imperative for the Government to get the bill passed during the winter session.

In pursuance of the TRIPs Agreement negotiated during the Uruguay Round, the Patents Act, 1970 was first amended in March 1999, to introduce the transitional (mailbox) facility from 1 January 1995, to receive and hold product patent applications in the fields of pharmaceuticals and agro-chemicals till 1 January 2005. The second amendment to the Act was incorporated in June 2002, to meet the obligations relating to the modifications in the provisions concerning issues such as the term of patent protection, rights of the patentee, and compulsory licensing.

The NDA leaders, during their interaction with Commerce and Industry Minister Kamal Nath urged him to factor in the concerns of the pharmaceutical industry and the common man if the claims for a product patent by a company were recognized and exclusive marketing rights (EMRs) granted to it. Prices of essential drugs may spiral, rendering them beyond the common man's reach, former union commerce minister Arun Jaitley (BJP) is learnt to have said.

As a way out, he suggested the rival companies may be granted the right to put in their objections after a firm was given the EMR for a product.

Shri Kamal Nath, while responding to suggestions by the NDA partners, assured that the proposed third amendment would fully take into account the public interest, including public health concerns, making full use of the flexibility available in this regard in the WTO Agreement on TRIPs.

There was a general consensus among the participants on the need to meet the international commitment of adhering to the deadline of 1 January 2005 for the introduction of product patents through legislation, while ensuring that mechanisms were put in place to safeguard public access to medicines at affordable prices.

(*The Economic Times*, 21 October 2004)

Pharma MNCs Push for Data Exclusivity

PHARMA multinationals have stepped up lobbying with the Government as the countdown for product patent regime has begun.

PhRMA, a US-based lobbying group of 68 top-notch MNCs, is leaving no stone unturned when it comes to pressuring New Delhi to have their IPR posers addressed. Its wishlist includes enactment of "data exclusivity" and getting patent amendment Act passed in the winter session of Parliament without any substantive modification of the draft at hand.

Interestingly, the multinationals have also opened a parallel channel with the "mighty Left" Representatives of PhRMA, whose member companies made a combined R&D investment of $33.2 billion in 2003 itself and over $32 billion the year before, met leaders of CPI.

A group of ministers headed by Defence Minister Pranab Mukherjee is currently reviewing the draft amidst conflicting demands from domestic firms and MNC pharma companies. The domestic companies want the Government to reduce the scope of patentability and restore the pre-grant patent opposition provision. MNCs would like the compulsory licensing proviso to be weakened.

The Government Departments had opined in their notes to a panel examining the data exclusivity demand that the existing provisions in the relevant pieces of legislation would suffice to meet India's obligation under Article 39.3 of TRIPs. These departments have agreed with the predominant view in the domestic pharma industry circles that data protection policies are a clear ploy for "ever-greening" of patents, which can extend the life of a patent even when the patent is invalidated and delay introduction of cheaper generic drugs. Data exclusivity is defined as protection for new drugs/ agrochemicals data furnished with the authorities for regulatory clearances, from "unfair commercial use" by anybody other than the innovator.

Given the positions taken by key ministries, what best the MNCs can now hope for is a mere protection of the data they furnish with the regulators from unfair commercial use by some legislative changes, other than in the Patents Act. That is, they would not, in any case, get what they really wanted, that is, a tool to extend the market exclusivity beyond the period of original patent protection.

"Our main concern now is to get the amended Patents Act approved by Parliament before 1 January '05 deadline. Even if our demand on data exclusivity is not addressed in the current draft bill, there is always scope for fine-tuning the Act later," says Rajiv Gulati, CMD, Eli Lilly India.

The Department for Industrial Policy and Promotion had noted that the MNC demand for data exclusivity is basically a supplementary move to secure market advantage over pharma products being marketed by Indian companies by using clinical trial data already available as any provision of data exclusivity will delay introduction of generic Indian products in the market and mean larger profits for MNCs. The DIPP also feels that such protection does not come under the purview of the patent law and the issue should be delinked from issue of patents protection and TRIPs.

The Department of Commerce quoting Uruguay Round talks had observed that negotiating parties considered fixed term data exclusivity in these talks but subsequently rejected the concept. Since TRIPs Agreement obliges enforcement of criminal procedures only in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale, for other, such as IPRs, civil and administrative procedures as laid down under Articles 42-49 of TRIPs Agreement was adequate, said the Commerce Department.

(*The Economic Times*, 19 October 2004)

US Declares War on Patent Theft

THE US Justice Department has outlined what it called its most sweeping crackdown on bootleg DVDs, fake designer goods, illegal music downloads and counterfeit drugs. Attorney General, John Ashcroft, announced measures to expand and strengthen specialist units to fight intellectual property crimes in the US and in Eastern Europe and Asia, where many counterfeit goods are made.

Mr. Ashcroft, speaking to reporters in Los Angeles, cited a new Justice Department report that estimates intellectual property theft worldwide costs US companies $250 billion a year. "Theft of this national resource has become an epidemic,'' Mr. Ashcroft said. "This represents a hemorrhaging of the work product of American citizens.''

He said the Motion Picture Association of America estimates that 2.6 billion songs, movies and software programmes are illegally distributed over the Internet every month. Counterfeit entertainment and luxury goods are only a small part of the problem. Thieves increasingly target prescription drugs such as Viagra, batteries and baby food, the Justice Department report said. It highlighted the case of an American teenager whose counterfeit cell phone battery exploded, causing a fire in his bedroom, and a man prosecuted for selling adulterated pesticides to city governments trying to control the spread of the West Nile virus.

Mr. Ashcroft said the Government will add five specialist units dedicated to identifying and prosecuting intellectual property suspects to the 13 already operating across the country. Federal prosecutors will go to US embassies in Hungary and Hong Kong to help with efforts in those countries, and the US will ensure that intellectual property crimes are included in all its international extradition treaties. Mr. Ashcroft said the FBI also would increase the number of agents assigned to investigations, and

develop youth information programmes to encourage respect for artists' rights. The measures represent "the most aggressive, most ambitious, most far-reaching law enforcement effort ever undertaken to protect intellectual property,'' he said.

(*The Economic Times*, 14 October 2004)

Emergency Drugs Must be Easily Available in Post-Patent Regime

KEEPING the Common Minimum Programme's (CMP) promise of affordable drugs in mind, the Ministry of Chemicals and Fertilizers has said that drugs needed for national calamities and emergency situations should be easily available even when the Patents Act comes into effect in 2005.

Certain drugs, which are protected by patent, must be made available through the compulsory licence route, said the Minister of Chemicals and Fertilizers, Ram Vilas Paswan, to the Group of Ministers (GoM) set up to look into the amendments to the Patents (Amendment) Bill 2004.

But there are differences between the Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers. Sources said, "The former is supportive of the Paris Convention on Intellectual Property Rights under which a cooling off period of three years is prescribed for the patent holder to launch the product. Under it if the patent holder fails to do so, the Government can give the drug to another manufacturer under the compulsory licensing clause. However, the chemicals and fertilizers industry prefers the TRIPs Agreement under which there is no cooling off period and compulsory licences can be issued to manufacturers during an emergency. The latter has pushed its case at the GoM meeting."

Shri Paswan pushed for prevention of evergreening of patents. "The Ministry wants to define patentability very clearly in order to prevent evergreening of patents. Companies could otherwise make small changes in the formulations and take the shield of patents," said the sources.

Another issue that the Ministry has flagged off is the large number of pharma patent applications filed in the mailbox facility. "Nearly 4,000 applications have been filed using the mailbox facility. But several of these molecules were invented pre-1995. The Ministry is of the view that since these molecules have been launched earlier, patents should not be granted to them," said sources.

The fourth area of discussion was the issue of pre-grant opposition to patents. The proposed amendment to Section 25 removes this right of hearing and provides it only post-grant opposition.

"Our Ministry feels that pre-grant opposition would help curb the fraudulent and frivolous patents. Hence, companies should be allowed to oppose patents before they are granted," said the Government source.

The domestic pharmaceutical industry has also been pitching for similar changes in the Patents Amendment Bill.

The Indian Pharmaceutical Alliance has said that the safeguards to prevent evergreening of patents, pre-grant opposition and careful scrutiny of the mailbox facility would help the domestic industry grow.

(*The Hindu Business Line*, 15 October 2004)

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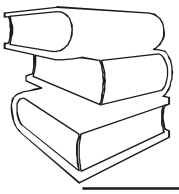

BOOKS/ARTICLES NOTES

BOOKS

Gearing Up for Patents: The Indian Scenario by Prabuddha Ganguli, Universities Press, Hyderabad, 1998.

THE publication focuses broadly on the present Indian patent system and operational procedures. It discusses the provisions of the Indian Patents Act, 1970. The provisions discussed include essential patent documents, opposition to patents and enforcement of patents, patents as a source of information and as a strategic tool, harmonization of patents systems and debatable issues pertaining to patents, and problems of having an appropriate legal system with respect to farmers' rights, transgenic plants and microbes, plants containing patented genes, protection to genes sequence, and new varieties of plants and issues related to biodiversity. Besides, the book contains a large number of case studies which illustrate different issues related with patents.

A Concise Guide to European Patents: Law and Practice by Gerald Paterson, Sweet & Maxwell, London, 1995.

AT the outset, the book states that since the opening of the European Patent Office in 1978, the European Patent System has developed impressively. The system is based on the European Patent Convention, a treaty signed by 17 European countries, which provides a centralized system for granting European patents.

It has been presented in nine chapters. Chapter I, entitled "Outline of the European Patent System" gives an outline of the special features of the European Patent System. Chapters II to V describe the examination, opposition and appeal procedures of the European Patent Office. Chapters VI to IX analyze the substantive jurisprudence governing the grant of European patents.

Law Relating to Patents, Trade Marks, Copyright & Designs by B.L. Wadhera, Universal Law Publishing Co. Pvt. Ltd., New Delhi, 1999.

THE book makes an attempt to discuss various aspects relating to patents, trade marks, copyright and designs. It has been presented in five parts. Part I captioned "Patents" describes various aspects relating to patents such as procedure for obtaining patent, rights conferred on patentee, transfer, infringement, action on infringement, patent in computer programmes, protection for micro-organism, etc. Part II entitled "Trade Marks" deals with registration, infringement and remedies against infringement, etc. under Trade Marks Law. Part III under the head "Copyright" deals with various issues relating to copyright in the areas of ownership, copyright, remedies against infringement, regulatory authorities, rights of broadcasting organization, copyright societies, and international copyright. Part IV captioned "Design" focuses on various topics connected with design, viz. registration, piracy of registered design, etc. The concluding part entitled "Trade-related Aspects of Intellectual Property Rights" contains a summary of the WTO Dispute Settlement Panel Reports, EMRs and its implications.

Integrating Public Health Concerns into Patent Legislation in Developing Countries by Carlos Correa, University of Buenos Aires, Argentina, 2000.

THE publication discusses about various options for the design and implementation of public health sensitive patent policies in developing countries. Further, it explains issues related to patent law which may help to strike a balance between the public and

private interests involved in the protection of health-related inventions, including those of states, and the suppliers of health-related goods and services. It also discusses the main issues to be considered with respect to the patentability of health-related products and processes. Finally, it presents key principles and options for the development of provisions in national patent laws. These principles aim to provide the basic concept on which detailed provisions could be fashioned after careful deliberation and consideration of the characteristics of each national legal system and patent law.

Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries by Joan-Roman Borrel and Jayashree Watal, Centre for India National Development, Harvard University, 30 May 2002.

THE publication makes an attempt to assess the impact of patents on unsubsidized access to a new drug therapy. Further elaborating on this, it says, that there can be two possible effects of patents on access to new drugs in developing countries. On the one hand, patents may constrain access to new drugs through less competition and higher prices and on the other, patents may promote access to new therapy by encouraging innovators to launch new drugs in low and middle income countries soon after introducing them in high income countries. Finally, it studies impact of the patents on unsubsidized access to ARV therapy in a sample of low and middle income countries in the 1990s.

TRIPs, PACT and Global Patent Procurement by Markus Nolff, Kluwer Law International, The Hague, 2001.

THE publication says that the introduction of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement has established a global patent system requiring a high standard of patent protection. However, any consequential increase in patent applications will further strain the resources of patent offices worldwide. A monolithic "World Patent Office" granting "World Patents" will most likely remain a utopian idea but the Patent Cooperation Treaty (PCT) has successfully demonstrated how to emulate a "World Patent Office" processing world patent applications. The current PCT only goes halfway towards the grant of a patent, where the logical step to handle an increase in patent applications would be focussed to further develop the PCT towards a patent grant procedure. This has been recognized and, in late 2000, the Assembly of the PCT Union decided to set up special body to consider a formal request by the United States for a "Reform of the Patent Cooperation Treaty".

Further, it says that analysis of TRIPs indicates that a patent procurement procedure minimizing prosecution efforts by WTO Members might be required to ensure that all WTO Members are able to satisfy the patent procurement requirements of TRIPs.

It has been presented in four parts. Part I analyzes the general effect of TRIPs on the global patent system. Part II reviews how the provisions of the TRIPs and the PCT compare and whether the two agreements are compatible with each other. Part III addresses possible alternatives to further develop international phase proceedings of the PCT. Part IV discusses how TRIPs affects the global patent procurement in general and in particular for the WTO Members and whether further development of the PCT might be the right approach for processing a large number of applications.

Indian Patents Law & Procedure by D.P. Mittal, Taxman Allied Services Pvt. Ltd. New Delhi, 2002.

DESCRIBING salient features of the Indian Patents Act, 1970 the publication says that the Act is designed to give primacy to social interest in the vital areas of food and medicine. That primacy has been under strain in view of the Uruguay Round Agreement and the Paris Convention. Under the Agreement, the law has to be modified by 2005. In the meantime, however, exclusive market rights have to be given. The Law was, therefore, amended by the Patents (Amendment) Act, 1999, which was made operative from 1st January 1995. Further, the publication makes an attempt to explain the Law of Patents in India in a simple language in the present global context, with the help of decisions of the Indian and foreign courts. It consists of 20 Chapters and 6 Appendices. As an introduction, there is a separate chapter in the beginning stating briefly the Government's efforts

to make India destination of foreign investment, the characteristics of the intellectual property and international treaties dealing with it.

Chapter 1 deals with patent system in India. An overview of the Indian Patents Act, 1970 is dealt with in Chapter 2; of the Patents (Amendment) Act, 1999, in Chapter 3; and, of patent under the Uruguay Round Agreement, in Chapter 4. Chapter 5 deals with patentable inventions. Chapter 6 deals with making application for the grant of a patents office to see whether it is in accordance with the requirements of the Act and whether there could be lawful objection to its grant. The matter is dealt with in Chapter 7. Chapter 8 deals with the exclusive market rights, which is the subject of the said Act. Opposition to grant of patent is dealt with in Chapter 9. Chapter 10 deals with grant and sealing of the patent. Patent rights are dealt with in Chapter 11; its working in Chapter 12; revocation and surrender in Chapter 13; infringement in Chapter 14. Powers of the Controller, Register of Patents and the establishment of the patent office are dealt with in Chapter 15. Penalties and prosecution are dealt with in Chapter 16 and the offences by the companies in Chapter 17. Chapter 18 deals with patents agents. Confidential information relating to patent is dealt with in Chapter 19. Chapter 20 deals such issues as historical background of the Paris Convention, 1883, basic Indian Patents Act, 1970, other intellectual property rights, GATT and intellectual property, Uruguay Round and GATT, Dunkel Draft Agreement, conclusion of Uruguay Round, India and Uruguay Round Agreement, World Trade Organization (WTO), World Intellectual Property Organization (WIPO), etc.

Understanding TRIPs: Managing Knowledge in Developing Countries by M.B. Rao and Manjula Guru, Responses Books, 2003.

THE book says that the ownership of intellectual property is an important concept that very often has international ramifications. In a world that is getting smaller every day, critical issues of intellectual property rights (IPRs) – especially those that deal with copyrights, patents and trade-marks and geographical indications – are gaining importance for global knowledge-based companies.

The book discusses in detail the controversial TRIPs (Trade Related Intellectual Property Rights) Agreement that was a result of the Uruguay Round Negotiations. TRIPs aims to strengthen IPRs by checking copying, piracy, illegal imports, and other violations. It also seeks better enforcement by strengthening the dispute settlement procedure. While everyone agrees on the need for protecting IPRs, the area of disagreement mainly centres around patent protection and the enforcement of rights. Further, it explains in detail TRIPs Agreement and its effects with special reference to developing countries. It critically examines the provisions of the Agreement articlewise. In addition, it discusses and analyzes numerous pertinent topics that include industrial design, the protection of undisclosed information, anti-competitive practices, Indian and other national laws on the subject and the Doha declaration and further negotiations on TRIPs.

The publication says that there is resentment in India over the TRIPs Agreement because it has given in to protection to product patent. Patents on products like basmati rice, neem, turmeric, and tea, having Indian origin, have been granted patents abroad.

Further, it says that a study of patents under the TRIPs Agreement is incomplete without reference to the "exclusive marketing rights" granted to the right holder. Those rights are not dealt with in Section 5 Part II of the Agreement dealing with patents, but under Article 70 in Part VIII of the Agreement dealing with "institutional arrangements".

An Introduction to the Guiding Principles in the Decisions on Patent Law compiled and edited by Dr K.V. Swaminathan, Bahri Brothers, and Waterfalls Institute of Technology Transfer, New Delhi 2000.

THE publication says that in the field of patents, compilation of recent cases decided in many countries will be of interest, particularly since in many countries their laws were modified or being modified to be in harmony with the requirements under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).

The book has attempted to put together a large number of typical cases together with the final verdict of the courts on them. The cases referred to have occurred in different parts of the world where the precise formulations of a certain legal provision would be different. However, many of these decisions are seen to have very many common factors and as such useful guiding principle can be drawn which will facilitate the broad appreciation of the basics involved. Recognizing that the TRIPs Agreement would perhaps constitute a broad basis on which many legal systems in different countries of the world would have adapted, the compilation, it says will prove very useful to the students of Intellectual Property Rights in the country.

The book contains over 100 cases from 15 countries. These cases have been arranged in 10 major headings so that the guiding principles involved in each group can be visualized very carefully. The first four groups have dealt with the basic requirements to obtain a patent, namely patentability, novelty, obviousness and extent of discloser. The next three groups deal with important aspects such as broad patents, doctoring of equivalents, compulsory licences, parallel imports & exhaustion as well as supplementary protection. The remaining three groups examine the type of legal disputes and remedies that follow in patent dispute resolution. They also describe a wide range of situations in which the decisions on infringement disputes are presented.

The book also contains three annexures. The first annexure presents three cases decided by the Appellate Body of WTO to illustrate that their decisions have a mandatory effect on the change to be made in the national law to ensure compliance with the TRIPs Agreement. The second annexure deals with the important recent developments on patenting of biotechnology and examines the patenting of business method practices. The third annexure is an index to the cases.

ARTICLES

Patent Regime: Many Issues Need Attention, *The Hindu Business Line*, 17 November 2004, p. 8.

THE article states that even as the country readies for the WTO-compliant product patent regime scheduled to start from 1st January 2005, many issues including data protection and quality of patents need to be attended to even after the Third Patent (Amendment) Bill is passed by Parliament. A new legal regime, it says, will soon be in place and more amendments are likely to come thereafter. Many new situations will arise from now on. More litigations are likely to come up given the fact that patent awareness is very low in the country. Further, it stresses the need to have new policy directions covering patent administration for quality control of patent grants and promoting commercialization.

The article also highlights views of the Minister of State for Science and Technology, Kapil Sibal, on the subject, who shared the same while addressing recently a conference organized jointly by FICCI and DSIR in New Delhi. The Minister called for the need to fully understand the implications of the patents to be granted. He opines that IPR must be made a compulsory subject in college law courses and in universities. The Minister also exhorted educational institutions, national laboratories and industrial R&D laboratories to gear up to generate IPRs that are worth protecting. In his concluding remark, he stressed the need to invest liberally to enhance the skills and knowledge base of scientists through structured in-house and external professional training programmes.

Don't Trip on Patents, *The Business Standard*, 28 October 2004, p. 7.

MAKING an observation at the outset, the article states that the Indian patent regime will undergo major change if the country manages to meet the 1st January 2005 deadline set under the TRIPs (Trade Related Intellectual Property Rights) Agreement to switch over to product patenting.

The article lays emphasis on carefully studying issues concerning the new enactment. The bulk of the patent applications currently lying in the mail

box, it says, are related to products like salts, distillates, isomers and the like. Many of these may not deserve to be protected by patent. The new law needs to make full use of the flexibilities allowed under the TRIPs accord. The proposed shift from process patents to product patents, it says, cannot be free of adjustment problems in many sectors. In the pharmaceutical sector alone, drugs worth an estimated Rs 3,000 crore are expected to go out of the market once a new law comes into force. To cope up with the new development, the article stresses that industry should gear itself to work under new regime.

Towards A Brave New World of Patented Knowledge by R.A. Mashelkar, *Observer of Business and Politics*, 8 February 1999, p.11.

THE article has been excerpted from the 16th Dr. C.D. Deshmukh Memorial Lecture on "Economics of Knowledge" delivered by the author at India International Centre, New Delhi on 14 January 1999.

The article suggests a suitable strategy for building up knowledge networks in the country, on the one hand, and role of IPRs in the economics of knowledge, on the other.

For building up knowledge networks, the article makes some suggestions. These include (a) use of publicly-funded R&D institutions as idea generators and providers of new concepts to the industry, (b) greater role to be played by the Indian industry as partners who have the technical, financial and marketing strengths to take ideas to the market-place, and (c) integration of national R&D resources by the Indian industry into their business strategy.

The article further points out that the CSIR as a large publicly funded R&D system has been making concerted efforts to make a cultural shift in the operations by looking at research as a business, thereby defining a new product, a new process and doing it in a business-like manner. The CSIR, it states, is hopeful that it will become an effective hub in the Indian knowledge network and play a crucial role in driving forward the issue of obtaining economic gains from a vibrant Indian knowledge bank. The CSIR's partners include giants such as Mobil, General Electric, Du Pont, Boeing, etc.

In the concluding remarks, the article lays emphasis on conceiving patents of shorter duration for smaller innovations including specific improvements in the traditional knowledge. This, it states, will give a boost to the creative capabilities of otherwise deprived innovators.

Patents May Kill Rs 3,000 cr Pharma Market, *The Economic Times*, 25 October 2004, p.4

THE article says that product patent regime to be ushered in from 1st January 2005 will gradually destroy Rs 3,000 crore worth of Indian pharma market. The Group of Ministers (GoM) on Patent Act Amendment, it says, have decided against allowing existing generic versions of patent products. So, as and when the Patents Controller accords patent to any of the over 4,700 applications currently locked in the mailbox, the generic producers of the drug will have to withdraw their products from the market. The patented drug can be far more expensive to the consumer than the local versions. Allowing the existing generic drugs in the product patent regime, it says, would violate the transition principle laid down in the TRIPs Agreement.

The GoM decision not to allow existing generic versions, after a patent is granted to the firm that discovered the drug, will be a double whammy for the Indian generic companies. These companies will not only have to stop selling the drugs in India, but also will not be allowed to make and export these drugs from India to countries where the drug is not patented.

Mailbox facility, it says, is designed to facilitate patent filings for drugs discovered between 1995 and 2005. The number of new chemical entities (NCEs) discovered during this period is around 135 only.

The Basmati Patent Issue by Surinder Sud, *Yojna*, June 1998.

THE article deals with patenting of aromatic basmati rice by the US Patent Office granted on 2 September 1997 to an American company Ricetec Inc. The patent states that the invention relates to a novel means for determining the cooking and starch properties of rice grains.

The article further says that the US company managed to get the patent by exploiting the differences in the provisions of the US and Indian patent laws.

The article stresses the need to initiate prompt action by the Government to expedite the enactment of long overdue Acts, viz. Biodiversity Act, Geographic Indications Appellation Act, Patents Act and the Plant Varieties and Farmers Protection Act.

Patenting A Non-Issue by Bibek Debroy, *Business Today*, 22 January 1999, p.44.

DESCRIBING the salient features of the present patent system in India, the article states that the Indian Patents Act, 1970 does not permit product patents. The duration of a patent is 5 years from the date of obtaining the patent or 7 years from the date of filing application.

As per the ruling of the Uruguay Round, the article states that by 2005, there will have to be product patents as well. Their duration will be for 20 years.

The article also dispels the fears that drug prices in India will match the levels prevailing in the US after product patents are introduced. These fears, it says, are totally exaggerated.

WTO-mandated Changes in the Patents Act by Biswajit Dhar, *The Economic Times*, 7 May 1999, p. 6

THE article states that in the year 2000, the Indian Patents Act would require a series of changes which are mandated by Article 65.4 of the TRIPs Agreement.

The article further observes that at least three aspects of the present Patents Act would need to be amended. The first pertains to the term of patents. The second relates to the nature of rights that the patent-owner would enjoy. And the last one pertains to the patentable subject matter indicating the fields of technology which the amended Patents Act would consider for granting patent rights.

The article also mentions that in the year 2000, the patents applied in India would qualify for a 20-year protection. The Indian Patents Act of 1970 provides patents for a shorter term of 7 years in the case of pharmaceuticals and agro-based chemicals, while all other fields of technology are given patents for 14 years.

The New Patents Regime under WTO: Implications for India's Pharmaceutical Sector by H.A.C. Prasad, *Global Economic Challenges in the New Millennium: India's Strategic Agenda*, Indian Institute of Foreign Trade, New Delhi, 1997.

THE article examines the implications for India's pharmaceutical sector in the new patents system under the TRIPs Agreement. It provides detailed analysis of the factors which may affect India's pharmaceutical sector. These include Most-Favoured-Nation (MFN) Treatment and Product Patent vs. Process Patent, New Exclusive Compulsory Licensing, and Reversal of the Burden of Proof in Process Patents, Exclusive Marketing Rights, Duration, Exhaustion & Enforcement of Patents, and Unilateralism.

In the concluding remarks, the article states that the new patents system under the WTO will not have much impact on India's pharmaceutical sector though it may not also be very rosy in terms of foreign investment and technology transfer. Further, the article observes that there are many clauses within and outside the TRIPs Agreement which can be used to India's advantage. India, it stresses, should invest heavily in R&D which is presently at an abysmally low level. This, it says, will help in securing more and more foreign patents for Indian products.

What Changes Does Our Patent Act Need?, *The Economic Times*, 21 December 2004, p.7

THE article contains views of three experts on the issue of patents. Sharing his views at the outset, Anand Grover, Advocate, Bombay High Court says that India has to introduce changes in its patent law by 1st January 2005, because of its obligations under the TRIPs Agreement. There are basically two types of patents—product and process. The protection of a product patent produces an absolute monopoly, stifles competition and permits high pricing. Process protection, however, allows for more than one producer, competition and restrains prices. That has

been the experience of the working of the Indian Patents Act, passed by Parliament in 1970 after much deliberation, and reports of two committees headed by eminent judges. Further, he says that the procedures provided for Compulsory Licensing are cumbersome and need to be simplified and made liberally applicable, based on a fixed percentage of royalty on the grant of patent.

Prabuddha Ganguli, CEO, Vision-IPR, opines that the Indian Patents Act is on the verge of another long awaited welcome track change to ensure enhanced protection of inventions by scrapping of Section 5 of the IPA (1970). That will allow product patents related to substances resulting from chemical reactions, pharmaceuticals, agro-chemicals and foods. The standard criteria for the patentability of inventions, he says, should be novelty, non-obviousness, i.e., the invention must have an inventive step and it must have usefulness, i.e., be capable of industrial application. India's key strengths are "incremental inventions", especially in pharmaceuticals and foods, etc. The new Act, he says, should also provide for transparent guidelines for the examination of patents with regard to software so that software patents do not get restricted only to embedded software. India, he says, provided for a mailbox provision with effect from 1st January 1995, in Section 5(2) of IPA (1970), after its first amendment. The new Act, he says, should lay clear guidelines with respect to the date from which any product patent will be effective, especially for mail-box applications since these were filed between 1st January 1995 and 1st January 2005 during which India had not granted product patents.

Finally, Ajit Dangi, Director General OPPI, says that India is becoming a destination of choice for outsourcing many pharmaceutical processes such as clinical trials, custom synthesis, bio-informatics, research & development (R&D), etc. For this process to gain momentum, it is important that the data generated in such activities need to be protected from unfair commercial use as it is an integral part of IPR. India should, therefore, opt for a minimum of five years of data protection as many developed countries do.

Govt May Amend Patents Law by Ordinance
by James Mathew and G. Ganapathy Subramaniam, *The Economic Times*, 3 December 2004, p. 8.

THE article says that in case product patents are not put in place by 1st January 2005 as committed by India to other members of the World Trade Organization (WTO), trade sanctions could affect exports. The first casualty could be scrapping of textile quotas with effect from 31st December 2004. The US and the European Union are not too happy with the scrapping of the textile quotas.

The US has already put some restrictions to check Chinese exports following pressure from the American industry. WTO members, it says, could also use other trade sanctions to block Indian exports. Finally, it says that India's hope of achieving strong growth in textile exports would be in jeopardy if trade sanctions result from the default on product patents.

Gene Revolution and Patent Rights
by K.P. Prabhakaran Nair, *The Hindu Business Line*, 12 October 2004, p. 8.

THE article opines that though patents have an important role to play, the main problem is the way a patent is manipulated by the agribusiness MNCs to their advantage. In the case of GM crops, the issue is different, but in no way less contentious because the patent-owning companies become all too powerful. India can learn a lesson from small countries such as Mexico, which said no to GM maize because the country is the origin of maize on no account. Courts cannot settle all the issues. Rather for India, the entire question must be nationally debated so that vested interests do not usurp what rightfully belongs to the public at large.

The implementation of international agreement on patent rights, such as the Trade Related Intellectual Property Rights (TRIPs) of the WTO, should remain sufficiently flexible to allow this debate to take place. It should also ensure that the economic and political interests of the poor farmers are adequately addressed.

WTO-TRIPs Obligations and Patent Amendments in India: A Critical Stocktaking by K.D. Raju, *Journal of Intellectual Property Rights*, New Delhi, Vol. 9, May 2004, pp. 226-241.

MAKING an observation at the outset, the article says that Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement was one of the most contentious issues in the Uruguay Round of multilateral trade negotiations. The commitments under the TRIPs Agreement compelled India to amend its patent regime in 1999, 2002 and 2003 (the Agreement Bill lapsed due to the dissolution of the Lok Sabha).

The article examines the amendments made in the Indian patent system in the TRIPs Agreement. India opted for setting up of a "mailbox" and took Exclusive Marketing Rights (EMR) route for the transitional period. Further, it provides an analyses of the implications of transitional period and suggests some options available to India. It also looks into the new provisions included in the Patents (Amendment) Bill 2003.

The Indian Patents Act, it says, has been amended a number of times to comply with the TRIPs Agreement. But still the management of the patent regime in India is not satisfactory. The pending patent applications are increasing day by day. Recently, India constituted a Patents Appellate Tribunal with appellate jurisdiction on the decision of the Patent Commissioners all over the country.

In its concluding remark, the article says that as a nation committed to the interests of its people, India has to use all options to minimize the lethal consequence of TRIPs regime.

Transparency Measures under Patent Law regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing by Martin A. Girsberger, *The Journal of World Intellectual Property*, Geneva (Switzerland), Vol. 7, No. 4, July 2004, pp. 451-480.

THE article makes an analysis about the issues arising with regard to three transparency measures proposed under patent law, i.e., the disclosure of the source, evidence of prior informed consent and benefit-sharing. This is based on the proposal submitted by Switzerland to the WIPO's Working Group on Reform of the Patent Cooperation Treaty (PCT Reform Working Group), and the proposal submitted by a group of mega-diverse countries, the African Group, and the European Communities (EC) and their Member States, to the TRIPs Council.

The article has been presented in seven parts. Part I summarizes the various proposals submitted by Switzerland to WIPO Working Group on Reform of the Patent Cooperation Treaty. Part II provides an overview of the policy objectives advanced in favour of the proposed measures. Part III describes the recent developments at the international level. Part IV discusses provisions of the international agreements relevant for transparency measures under patent laws. Part V analyzes the various issues arising with regard to the three main patent-related transparency measures, i.e., disclosing the source of genetic resources and traditional knowledge; providing evidence of fair and equitable benefit-sharing in patent applications.

Further, it says that patent applicants may not be in a position to provide the required evidence and would be excluded from patent protection. Requiring patent applicants to provide evidence of prior informed consent would thus deviate from the obligations of Article 8(j) and of the International Treaty respectively. For several reasons, this burdens patent authorities with substantial administrative work and poses legal and practical problems.

Product Patents: Far from Public Good? by K.P. Prabhakaran Nair, *The Hindu Business Line*, 24 December 2004, p. 9.

THE article says that since WTO itself is currently reviewing the issue of patenting of "micro-organisms" and "non-biological and micro-biological processes", India need not pre-judge the issue against the nation's interests by declaring them patentable. Compulsory licensing is permitted within the framework of TRIPs Articles 31(a) and 31(b). This omission from the proposed amendment must be remedied forthwith.

Further, it stresses the need to (i) take a serious re-look at the entire question of drug prices; (ii) set

up a semi-statutory body, a sort of "Empowered Committee", to handle all matters connected with life-and-death issues. In its concluding remark, it says that a fundamental question India must address is how it can harmonize its national developmental strategies and global processes and disciplines and bring about a synergy among the different sectors of global economy which clearly impact India's developmental aspirations.

A New Prescription for MNC Pharma Firms,
The Financial Express, 26 December 2004, p. 5.

IN its opening remark, the article says that India's transition to the product patent regime from 1st January 2005 and its demonstrated strengths as a skilled and cost-competitive base for pharmaceutical and manufacturing and research have created a new set of growth opportunities for multinational pharmaceutical players, which can have a defining impact on their future prospects. The advent of the product patent regime, it says, promises a new growth era for the multinational pharma majors. The regime is expected to provide strong standards of intellectual property protection to innovator drug companies. Complemented by India's large population and low healthcare penetration, this provides a huge market opportunity to global pharmaceutical companies to launch their innovator drugs in the country.

Further, it says that the shape and form in which India will implement the World Trade Organization's (WTO) regulations are still uncertain.

The Indian pharmaceutical market which has been a generics market so far, will become aligned to the global market-place once the product patent regime is put into place. As a result, innovator drugs will compete in India too. Pharma multinationals do not conduct any significant research on their own in India and rely instead on their parents' product portfolio.

For A Development-Oriented TRIPs
by Ashok Khemka, *The Economic Times*,
27 December 2004, p. 3.

GIVING a brief background of the Patent Bill, the article says that the Third Patent (Amendment) Bill, meant to fulfil its obligation to introduce product patent protection in drugs, and medicines in compliance with Article 27.1 of the TRIPs Agreement falling due on 1st January 2005, was to be introduced in the winter session of Parliament. Serious concerns are being raised by various civil society organizations and NGOs against the proposed move. A major concern is the prices of drugs to our consumers, besides increased costs of administering and enforcing the patent system. The world consumers too stand to suffer in terms of possible higher prices of the generic drugs from India. Also, if product patents result in local production being replaced by imports, then the welfare loss to the consumers is further worsened by loss of employment and self-sufficiency.

Further, it says that it may be well understood that any failure to meet with the TRIPs obligations could be an excuse for the US and EU to take retaliatory action by continuing with the textile quotas due for removal from the next year. A quota-free regime in textiles is expected to benefit the textile industry of both China and India in the global market substantially. With its relatively lower costs of R&D, a vast pool of scientific manpower and abundant supply of technical skilled labour, India has the potential of being a global giant in the area of discovery and development of new drugs and can be the global hub of R&D-based pharma sector. This could turn out to be the next big story after the IT/BPO boom resulting in a large number of joint ventures and research collaboration projects between Indian biotech firms and large pharma companies. The issue of compliance with TRIPs, therefore, cannot be looked in isolation. In view of serious concerns, it seems more appropriate to adopt the Ordinance route now to grant product patents to drugs in compliance with our TRIPs obligations, before firming up final amendments to the existing Patents Act.

The main goal of TRIPs is to reduce distortion and impediments to international trade. Though IPRs are private rights, the underlying public policy objectives including developmental and technological development are recognized in the agreement itself. Under the TRIPs provisions, countries can adopt a variety of measures in formulating their legislation in accordance with the objectives and principles laid down in Articles 7 and 8 respectively.

Finally, the article says that measures like patenting new use of old drugs (proposed amendment to Section 3 (d)) and doing away with pre-grant opposition to patents should not be allowed under pressure from developed countries. There are at present 6,000 applications in the mailbox. In the absence of Section 25 allowing for opposition to grant of patents, there would be no proper public scrutiny before grant of patents. Finally, a wider pre-amendment debate is called for amongst all concerned to take the fullest advantage of TRIPs' provisions.

Is India Ready for New Patent Regime?, *The Business Standard*, 15 December 2004, p. 8.

THE article contains views of Sanjiv D. Kaul, Management Advisor, ChrysCapital and Harinder S. Sikka, Senior President, Corporate Nicholas Piramal India Ltd on the subject of patent. Sharing his views at the first instance, Shri Kaul says that India is ready for the patent regime and for all the challenges and opportunities it brings. It now needs to speed up the implementation process, particularly in terms of regulatory compliance and legal infrastructure.

Sharing his views on the subject, Shri Sikka says that patents are here to stay. The Government, therefore, should be addressing this fact rather than wasting time in listening to those with vested interests.

The government machinery on its own, he says, has not taken any concrete steps in setting up infrastructure to challenge the related workload. The arrival of the new patent regime has been known to us for long. Safeguarding intellectual property and patents, he says, will help us increase our strength to compete. Alliances, contracts, collaborations and frequent interactions with multinationals not only increase the free flow of ideas, they also give birth to new industries and, thus to employment. It is in India's interest to address the subject positively.

Patent Ordinance Eases Processing, Removes Exclusive Marketing Rights, *The Financial Express*, 28 December 2004, p.4.

THE article highlights salient features of the new patents ordinance. Under this ordinance, the Government introduced product patenting in pharma, food and chemicals effective from 1 January 2005, rationalized and reduced the time-frame for processing patent applications and did away with the transitional provision of exclusive marketing rights.

Some of the salient features of the Patents Ordinance are as under:

- Software would now be patentable if embedded with hardware. Currently, the intellectual property rights (IPR) protection with regard to software is limited to copyrights.
- The rights of mailbox applicants have now been rendered "prospectively operational only," that is, only from the date of grant of the patent and not retrospectively from the date of publication. Mailbox is a facility introduced in the Patents Act through the first amendment in 1999, allowing anybody to apply for patents for inventions made during 1995-2005.
- The ordinance seeks to retain definite time limit (90 days) pre-grant provision, which the earlier draft sought to dilute within a week. However, the opposition would now be allowed only on the ground of "patentability".
- Indians wanting to file for patents abroad will need a no-objection certificate from the Indian government. This provision has been included specifically to guard against patenting of dual use of technologies.
- Compulsory licence which is a facility with the governments to sidestep patents under defined circumstances can now be issued without the grace period of three years from the grant of patent.

Patent Truths, *The Financial Express*, 29 December 2004, p. 6.

THE article says that the amendment to the Indian Patents Act, 1970 clears the air on one of the most contentious issues in recent years: the changeover in our patent regime. The amendment (the third and most significant to date) heralds the transition from a process to a product patent regime for pharmaceuticals, chemicals and food by 1st January 2005 and is in line with our obligations under the WTO's TRIPs Agreement.

The Ordinance addresses many of the concerns voiced by the Left and domestic industry. Thus, it does away with the proposal to allow open-ended pre-grant opposition and fixes a time-bound (90 days) period for all pre-grant opposition. Such opposition, it says, will only be allowed on grounds of "patentability". Post-grant, a patent can be opposed before the Patents Controller in the court of law. The rights of mailbox applicants (those who had submitted their patent applications under the mailbox facility established after the 1999 amendment) will be operational only from the date of grant of the patent and not retrospectively. This takes care of a major concern of generic producers who feared that they would be hauled to court for patent violations in case the benefit is extended retrospectively.

Contrary to widespread belief, the new regime is unlikely to see drug prices shoot through the roof as 97 per cent of drugs are off-patent. The other safeguards include retention of 13 compulsory licensing provisions including one for enabling grant of compulsory licensing for export of medicines to countries which have no manufacturing capacity. Additionally, compulsory licence – a facility to sidestep patents under specified circumstances – can now be issued within the grace period of three years from the grant of patent. The transitional arrangement of EMRs has been dropped. Embedded software can now be patented – a major comfort factor when India's software industry is moving up the value chain and developing potentially patentable software.

Strike a Balance on Product Patents
by D.G. Shah, *The Financial Express*,
29 December 2004, p. 7.

SHARING its views at the outset, the article says that the debate is not about whether to have product patent or not, but about the type of regime that India should have. It is about having a law that not only protects new inventions but also domestic companies from exporting off-patent products to global generics market. The issue is: Should India follow the perverse intellectual property rights (IPR) laws and practices of the US, EU and Japan or evolve its own IPR law utilizing flexibilities built in the Trade Related Intellectual Property Rights (TRIPs) Agreement?

India is in a unique position. It is alone among developing country producers of pharmaceuticals to have taken full advantage of the transitional arrangements under the TRIPs Agreement. It has emerged as the principle supplier of low cost pharmaceuticals not only for its people but also for most of the developing world. It has to demonstrate to the world not a "world class regime", as some in the government have claimed, but a "TRIPs-compliant regime" that restores the balance between the interests of the innovator and the consumer.

To develop an appropriate regime in the country, it further says, needs people with clarity in mind on the objectives of the IPR law and larger national interest at heart. The law will have to strike a balance between (a) promoting research and protecting access to medicines; and (b) attracting foreign investment in research and preventing flight of investment in the manufacturing sector to neighbouring countries with extended transitional agreements; and (c) leveraging the knowledge base for potential rewards and ensuring a dominant position in the global generics market. These, it says, require a careful assessment of the opportunity in the global generics market, the current state of the domestic industry and the national health.

The other critical component of the new law will be the ability to challenge patent before it is granted, knowledge about technical parlance as pre-grant opposition. The number of applications suggest that many are for marginal changes in the pre-1995 inventions, which are not eligible for patent-protection in India as per the TRIPs Agreement. Now, for any reason such as inadequate skill, in-experience or lack of integrity, if these applications were granted patents, domestic manufacturers will be forced to withdraw a number of medicines currently in the market, as in the case of imatinib mesylate (Glivec), resulting in non-availability and steep price increase. The remedy to this lies in retaining the existing provision of pre-grant opposition.

Patents Offices Need to Gear Up
by Mamta Singh, *Business Standard*,
29 December 2004, p.3.

IN its opening remarks, the article says that the Ordinance introducing the product patents regime

in pharmaceuticals, agro-chemicals and food is in place, but India needs to do much more to equip its patents offices to handle the rush of applications. The main issue, it says, could turn out to be the quality of examiners the country has.

Further, it says that the people who file patents applications want them examined. Patents are often filed for priority. Examination fees are fairly high world over, and not more than 10 per cent of the applications go in for examination.

Under the Indian laws, an applicant has 36 months to file an application for examination.

However, in addition to 12,000 pending applications, at least another 15,000 are expected to come under the purview of the Patent Cooperation Treaty to which India is a signatory.

To increase the speed for disposing of the patents applications, the Government has gone in for computerization of patents offices and created new posts for patents examiners. In the current fiscal, the Government provided Rs 12 crore for the Controller General of Patents, Designs and Trade Marks, and Rs 19 crore for modernization and strengthening of the patents offices and Rs 1.2 crore for the Intellectual Property Appellate Board (IPAB).

The Rs 44-crore computerization programme to upgrade four patents offices is expected to be completed in the next fiscal. The new offices in Delhi and Kolkata are expected to be ready in the next 4-5 months and in Chennai and Mumbai by July 2006.

Product Patents: Pharma Sector Optimistic About New Opportunities

by James J. Nedumpara, *The Financial Express*, 29 October 2004, p. 7.

PRODUCT patents in the pharma sector has become the norm in almost all countries and India has joined the bandwagon. The question, therefore, is how the industry, the government and consumers should respond to the new regime.

Product patents on pharma products, it says, were abolished in India in 1972. Since then, domestic firms have a firm footing in the market, their share having risen from 10 per cent in the early 1970s to nearly 80 per cent now. In fact, India and Japan are the only two countries where western MNCs do not dominate. India is also a major international supplier of drugs. This shows the pharma industry prospered under an environment which did not recognize product patents.

One then has to ask if a product patents regime will help Indian pharma. In the long term, it could. But in the short term, this is doubtful, if one looks at the statistics on current R&D spending. The cost of drug development is estimated at around $880 million, or nearly Rs 4,000 crore, while the annual R&D spending of the entire Indian pharma sector is only around Rs 800 crore. The development time for a drug is also relatively high, around 10-14 years. And, only 30 per cent of drugs have recouped these costs.

The Indian industry, it further says, is also one of the most cost effective manufacturers of generic drugs and will continue to thrive. The main factors behind this include strong vertical integration, excellent chemical industry infrastructure, abundant scientific talent, etc.

In its concluding remarks, it says that the beneficiaries of product patents will have to ensure that the pricing doesn't deprive the needy of medicines at affordable prices. This would require a leap of faith for consumers. The government has a role to play in cases where the industry reneges from social obligations. The government should, in addition to framing a viable and effective set of complementary policies, retain room for such intervention as may be called for.

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DOCUMENTS

STATEMENT BY SHRI KAMAL NATH, UNION MINISTER OF COMMERCE & INDUSTRY, GOVERNMENT OF INDIA

The Ordinance Relating to Patents (Third) Amendment

THE following is the text of the statement made by Shri Kamal Nath, Union Minister of Commerce & Industry, Government of India, on the Ordinance relating to Patents (Third) Amendment at a news conference on 27 December 2004 in New Delhi:

1. With the coming of the New Year, two significant developments in the world of commerce and industry open themselves to India. Both are connected with the world trading order, of which India is a part: one is the final phase-out of the Multi-Fibre Agreement, and the other is marked by India's conformity with the international Intellectual Property System in all respects, on terms that are practical and credible.

2. When India decided ten years ago to accept and adopt the world trading order, we committed ourselves to fulfilling certain obligations on the understanding that other countries of the world too would commit themselves to the same obligations. And out of these common commitments would arise opportunities – opportunities that would not have come our way had we stayed outside the system.

3. The WTO system provides an organized multilateral framework within which India can claim trade demands as a legitimate right; and in this we have succeeded. Ten years ago, our exports stood at less than 32 billion dollars. A decade later they had doubled to 64 billion dollars. Now we look to doubling our exports in five years. This year we are already set to cross 75 billion dollars. All this translates into more employment opportunities and greater economic activity, with its concurrent benefits.

4. It must be remembered that it is not only India that is conforming – for every commitment of ours, there is a parallel commitment of other member States. Because of our stand on special and differential treatment, our major trading partners have had to reduce their tariffs to a greater extent. Where dissatisfied, we have recourse to the Dispute Settlement Mechanism of the WTO. Of the 22 cases involving India which have so far been decided, India has won 9, and 7 were amicably settled on terms favourable to us.

5. The pharma industry and the IT industry are the two sunrise sectors for India. The ordinance amending the Patents Act provides for an enabling environment for both of these. Among the sectors that have experienced the greatest transformation in India, the Pharmaceutical Industry is perhaps the most significant. India's WTO involvement during the last decade has encouraged our pharma companies to adopt a strategy of R&D based innovative growth. Thus, while Indian companies spent not even a fraction of a per cent on R&D ten years ago, today the larger Indian companies are spending in the region of 6 to 8 per cent of their turnover on R&D. (The norm for major MNCs is 12%). The transformed Indian pharma industry is itself looking for patent protection – particularly

the bio-tech sector, in which India has aggressive prospects.

6. When we joined the WTO ten years ago Indian pharma exports were less than Rs 4,000 crore. A decade later our pharma exports are Rs 14,000 crore, and account for more than a third of the industry's turnover. This is the result of the confidence built up in our industry due to our progressive adherence to our IP commitments. Now we are poised to achieve an annual compounded growth rate of 30 per cent in order to double our pharma exports in three years. Some US$60 billion worth of drugs are going off patent in the next few years. Indian industry can grab a lion's share of this – provided we are a bona fide member of the international trading community, and are not in a questionable position, open to the possibility of retaliatory measures and sanctions, threatening not only our pharma exports, but other sectors as well – including our textiles sector.

7. Apart from manufacture of drugs, the pharma industry offers huge scope for outsourcing of clinical research. We have a vast pool of scientific and technical personnel, and recognized expertise in medical treatment and health care. India can take advantage of our strength in this provided we have the right legal framework in place, which provides IP protection to the results of that research.

8. In IT, the trend is to have software in combination with or embedded in hardware – such as in computers or cell phones or a variety of other gadgets. Software as such has no patent protection (the protection available is by way of copyright); but the changing technological environment has made it necessary to provide for patents when software has technical applications in industry in combination with hardware. This has been a demand of NASSCOM.

9. This Third Amendment is only the culmination of a process begun ten years ago. The provisions of the ordinance are to be seen in conjunction with, and in the context of the Act, as well as of the earlier two Amendments of 1999 and 2002. Our Patents Act always provided for process patents in all fields, and product patents in all fields except drugs, food and chemicals. The Act had to be amended in order to provide for product patents in these also with effect from 1st January 2005. A Bill had been introduced in Parliament a year ago by the previous government, but lapsed.

10. The new Government set up a Group of Ministers on the matter. It was our desire to bring the Bill to Parliament first. But it was also necessary to consult with all stakeholders and political parties. The last comments we received were on the 21st of December – and so it was not possible to bring the Bill to this session of Parliament. This has necessitated the ordinance. The ordinance will be discussed in detail in Parliament in the Budget session. The ordinance is an interim measure to fulfill our legal obligations within the stipulated time.

11. The ordinance is the same as the Bill introduced last year with improvements in some significant respects. We have introduced a provision for patenting of software that is embedded in hardware. We have also provided for a definite pre-grant opposition procedure. The earlier bill had only a post-grant opposition, with a weak pre-grant representation. After extensive discussions we have decided to have both pre-grant as well as post-grant opposition. Of course, we have rationalized the timelines, so as not leave everything open-ended, but have a definite time-table within which each of the stages should take place. This reduces by half the maximum time it would take for the processing of an application, from more than nine years to about four. Another significant modification is the introduction of a provision to protect Indian industry from infringement proceedings with retrospective effect. We have specifically provided that patent rights for mail- box applications will only be available prospectively. We have made these changes after wide consultation, and we feel that these considerably improve the proposals.

12. The fear that prices of medicines will spiral is unfounded. In the first place we must realize the fact that 97 per cent of all drugs manufactured in India are off-patent, and so will remain unaffected. These cover all the life-saving drugs, as well as medicines of daily use for common aliments. In the patented drugs also, in most cases there are always alternatives available. In fact a feature of patent protection is that it spurs research, so that constantly alternatives keep appearing in the market – and often the alternatives are better ones. Thus price control is inherently built in.

13. We have 13 Compulsory Licensing provisions under Chapter XVI in place. The Joint Parliamentary Committee discussed this issue threadbare three years ago. Their recommendations were the basis of the Second Amendment. The Act also has strong provisions under Chapter XVII for outright acquisition of the patent to meet national requirements. There is also the Drug Price Control Order administered by the National Pharmaceuticals Price Authority. With this framework in place it is clear that the concerns and fears expressed by various sections are wholly misplaced.

14. The Act ensures that the reasonable requirements of the public with respect to availability and affordability are taken care of. Public interest particularly public health and nutrition is protected. The law effectively balances and calibrates Intellectual Property protection with public health concerns and national security. By participating in the international system of intellectual property protection, India unlocks for itself vast opportunities in both exports as well as its potential to become a global hub in the area of R&D based clinical research outsourcing, particularly in the area of bio-technology.

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