Institute of Intellectual Property Development (IIPD)

The Institute is established under the leadership of one of the outstanding entrepreneurs of India, Dr K Anji Reddy, Chairman of Dr Reddy’s Research Foundation, and a leading scientist, Dr R A Mashelkar, Director-General, Council of Scientific and Industrial Research. This IPR institute is actively supported by the leaders of industry and scientific establishments.

The IIPD aims to disseminate information on all matters connected with providing training in the field of intellectual property research and management, give advice and assistance to people in management, education, business and any other profession related to intellectual property development and to cooperate with Central and State Governments or local bodies whenever and wherever necessary to promote the objects of the society.

A modern, well equipped building in line with similar IPR institutes the world over will come up shortly at Hyderabad.

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Plan to revise patent system

The Prime Minister, Shri I K Gujral has given the permission to revise the patent system in the country in a meeting of the members of the Scientific Advisory Committee to the Cabinet (SAC-C) held on 5 July 1997. Dr C N R Rao, Chairman of SAC-C would head the expert group comprising former foreign secretary, Shri Muchkund Dubey; former commerce secretary, Shri A V Ganesan; Disinvestment Commission chairman, Shri G V Ramakrishna; Planning Commission member, Shri S P Shukla; legal expert, Shri Fali S Nariman; Prof M G K Menon, Dr Rakesh Mohan of NCEAR, Dr Parvinder Singh of Ranbaxy, and Industrial Development Secretary, Shri P G Mankad. The project costing Rs 65 crores aims at removing various deficiencies in the system, which results in subsequent delay in the processing of patent application. It is expected to be implemented within three years. Presently it takes nearly three years to take up the patent application and 8 years to give the final decision as against two years in US.

The rate of filing the applications is increasing because of the awareness among scientists on the importance of patenting as a means for protecting their IPR. The backlog is expected to increase further. As against a capacity to process 2,000-3,000 applications per year, the number of applications filed during 1996 were 7,000 and is expected to go to 10,000 in 1997 and 30,000 in the year 2000.

Till now in most of the patent offices in Delhi, Chennai, Mumbai and Calcutta operation is manual and there are only 44 patent examiners. To make the process of patenting faster and easier, patenting system is being changed to electronic form and CD-ROM form (The Hindu, 7.9.97).
EU patent directive

On July 16, the European Union Directive on the Legal Protection of Biotechnological Inventions went before the European Parliament (EP; Strasbourg, France). The directive will unblock the logjam of genetic inventions at the European Patent Office (EPO; Munich) and remove some of the obstacles that have hampered EPO decision-making. This should be last hurdle for the directive after 10 years in a limbo created by parliamentary muscle-flexing and inordinate commission flexibility. The European Commission (EC) redrafted the original directive in 1996 after the EP initially rejected it in 1995; the version before parliament last month contains 63 additional amendments. Among the most important are the tight definitions that apply to human material sequences, or partial gene sequences, can be patented if isolated from the body and if an industrial application is disclosed. The directive also follows the recommendations of EC ethical advisers and specifically excludes from patentability “procedures for human reproductive cloning” and methods for artificially producing “human embryos containing the same genetic material as another human being or dead person”. Furthermore, it bans patents on animal germline engineering that might cause the animals to suffer without “substantial medical benefits” [Nat. Biotechnol, 15(8) 1997].

WTO rules against India on patents issue

US had filed a complaint in July 1996 and the European Union in May 1997 to WTO that Indian patent laws were inadequate. In August '97, the trade body ruled that India had failed to set up a mechanism to fulfil WTO obligations. India will now have to accede to WTO rules and introduce the pending patents (amendment) bill quickly to avoid retaliation by the US and EU nations. However, the present interim ruling of the WTO dispute settlement panel will be followed by a final report. India has the option to appeal against the report. If it does, the government will get another two or three months to pass the bill. If the WTO rules against the appeal, the US or EU nations can retaliate through sanctions like the withdrawal of Most Favoured Nation (MFN) status, or embargoes (Business World, 7 Sept '97, 41).

Towards modernization of patent offices

The government is finally modernizing India’s decrepit patent offices. The National Productivity Council has submitted a feasibility report to the industry ministry on this. The ministry has also called in two experts from the Geneva-based World Intellectual Property Organization for the purpose.

A budget of about Rs 65 crore is being set aside in the ninth plan for the modernization. The aim is to upgrade the offices and cut the time it takes to scrutinise patents. Now, it takes about four-six years after application to grant a patent. The ministry wants to bring this waiting period down to two years. One of the reasons of long wait is manpower shortage. The Patent Cooperation Treaty, which India has yet to sign, requires a country to have a minimum of 100 patent examiners. But India has just about 38. The ministry will finalise the plans in about two months (Business World, 7 Sept '97, 27).

EPO patent data

In order to encourage innovation in Europe, the EPO has reduced fees to inventors by 20 per cent. It will make its patent data available to searchers at “marginal cost”. Details of
this are still being finalised but the EPO already has the only system in the world which allows its examiners to check the novelty of a new invention with a completely paperless search.


Global software piracy continues to rise

According to one study, the illegal copying and distribution of computer software increased by 20% last year and accounted for an estimated $11,220 million in lost revenues worldwide. The study found that while piracy rates are declining, the total number of pirated software units continues to grow.

Of 523 million new business software applications used globally in 1996, 225 million units — nearly one in two — were pirated, according to the study released by the Business Software Publishers Association (BSA).

Eastern Europe continued to have the highest piracy rates, with an overall average of 80%, while North America’s 28 per cent rate was the world’s lowest. Western Europe had a piracy rate of 43%, Latin America 74%, and Asia-Pacific region 55%.

The United States had the lowest piracy rate of any individual nation (27%), but the highest revenue losses — an estimated $2,300 million in 1996. One out of every five dollars losses occurred in the Asia-Pacific area, with an estimated $3,700 million in lost revenues due to piracy.

Revenue losses in Japan were about $1,200 million, in India $255 million, in China $700 million, and in Korea $515 million.

Individual countries found to have high piracy rates include Vietnam (99%), China (96%), Oman (95%), and Russia (91%).

Low national rates were found in the United States (27%), Australia (32%), the United Kingdom (34%), Denmark (35%), New Zealand (35%), and Germany (36%).

The declining trend in the piracy is being observed in following regions:

In the Asia-Pacific region, piracy rates declined from 64% in 1995 to 55% in 1996. In Eastern European countries, piracy rate fell from 83% in 1995 to 80% in 1996. Piracy rates in Middle East and Africa dropped from 78% to 74%. South Africa showed a big improvement from 58% to 49%.

The lower piracy rate for most regions reflected a new environment that acknowledges the need to protect intellectual property and to sanction piracy (Economic News, May-June 1997).

Patent dispute on polyethylene technology

The long-running dispute between the Union Carbide and BP Chemicals goes back to 1985 when Carbide was first awarded a patent in US for condensation technology.

Carbide’s condensed mode technology adds a small amount of liquid to the recycle gas stream in the reactor to increase cooling capacity. This allows capacity to be increased and the more efficient production of higher alpha-olefin resins. Exxon took this a step further with its supercondensed mode to increase cooling and expand capacity. A patent dispute between Carbide and Exxon over this development was later settled.
when the two companies formed Univation Technologies.

Recently, a suit was brought by Carbide against BP in the UK High Court alleging infringement of its patents on condensation mode technology. Besides, Union Carbide is currently pursuing a case against BP in France for patent infringement at its Lavera plant.

In its decision, the UK High Court ruled that Carbide’s condensation patents were valid and that BP’s use of condensation technology in its Grangemouth gas-phase polyethylene plant, before the introduction of its high productivity technology in 1995, did infringe the patents. However, BP’s high productivity technology as currently operated at Grangemouth did not infringe the patent [European Chem News, 68 (1776) 1997, 49].

**UK patent office on web**


Held on the Patent Office’s own Web server, and developed in consultation with patent and trademark experts and interested parties, the site would update on the same day, news or other information available.

The home page offers links into sections on copyright, designs, patents and trademarks, each of which carry a description of the nature of these rights, and contacts for further reference. The home page also links to a newcomer’s guide, contact details, news pages, publications, prices and commercial search services and a ‘Focus’ section on a particular technology, the first of which is the “widget” (or device for promoting froth).

The Patent Office would shortly develop interactive elements within the site, including publication of the trademark classification guide, links to news groups and access to the patent and trademark databases [Patent World, 94 (1997), 11].

**US patent for CD-Tagging technology**

Vyrex Corporation, CA, has received a patent from the US Patent and Trademark Office for its CD-Tagging technology.

CD-Tagging is a comprehensive system to explore the structure and function of the genome and it could have tremendous power as a tool for gene discovery. “In contrast to other technologies, CD-Tagging can simultaneously tag a gene, its mRNA and its protein product”, said Dr Sheldon S Hendler, MD, Chairman and CEO of Vyrex. This occurs via recombinatorial events at the DNA level and can be used to analyze known genes and gene products, as well as to identify and characterize new genes. It also provides a method to easily isolate and purify protein products and determine their function”.

The CD-Tagging technology was invented by Dr Jonathan Jarvik, Vice President of biology at Vyrex. Vyrex holds an exclusive, long-term licence covering the CD-Tagging technology, including patents and know-how. This technology provides the ability to analyze genes and their protein products in their natural environment. It also has several advantages such as high throughput, tissue specificity, protein localization and immediate access to transgenic animals. Dr Jarvik’s team has obtained proof-of-principle in a number of organisms and cell types.

According to Vyrex, the CD-Tagging technology is broadly applicable to gene and
protein discovery in most organisms including plants and animals, but presently is focusing on the mouse and man.

Dr Hendler said that they intend to use this new and exciting gene discovery platform to explore mechanisms of oxidative processes in the body, including aging. They believed that the CD-Tagging technology, combined with small molecule drug discovery programme, would place them at the forefront of research into cell maintenance and repair. It would enable them to identify new targets relating to free-radical damage in cells and tissues, and might lead to the development of new and promising compounds.

Vyrex is developing therapeutic products including redox modulators, which are designed to promote cell maintenance and repair by reducing the damaging effects of free radicals. Therapeutic targets include infectious diseases, cancer, ear disorders, and respiratory, cardiovascular and neurodegenerative diseases [Biotech Pat News, 11(2) 1997,4].

US patent for treatment of Dupuytren's disease

Biospecifics Technologies Corporation, New York, has been granted a US patent for the use of its collagenase enzyme to treat Dupuytren's disease. It is a deforming condition of the hand in which one or more fingers, usually the ring and pinkie finger, contract towards the palm, often resulting in functional disability. It predominantly affects elderly male caucasians, often is linked to heredity, and has strong association with diabetes, alcohol consumption, cigarette smoking and HIV infection.

Dupuytren's disease is a European disease, rarely seen in non-caucasian races. It is most prevalent among people of Celtic and Northern European descent. The incidence of the disease can reach 20-25% of a mostly male, Northern European population between the ages 60-70. Well known people with Dupuytren's disease include former United States President, Ronald Reagan and former British Prime Minister, Margaret Thatcher.

A Phase I clinical study has been initiated with collagenase injection for treatment for Dupuytren's disease. Currently the only available and proven therapy for Dupuytren's disease is surgery involving the removal of the collagen bands responsible for the hand deformity. If clinical trials establish efficacy, treatment with collagenase injection for Dupuytren's disease would be an alternative to surgery and performed as an outpatient procedure.

Collagen is the main protein constituent of skin, cartilage, bone, and other connective tissue. More than a third of the body's protein is collagen and it makes up 75% of skin. Collagen is essential for binding cell to cell. Collagenase, an enzyme, works by removing the unwanted collagen responsible for certain disease and medical conditions. Biospecifics has pioneered the application of collagenase to certain disease conditions, and its strategy calls for the application of the enzyme to conditions where current remedies are deficient or non-existent. [Biotech Pat News, 11(2) 1997,2].

Transgenic wheat patent

Novartis Corporation, MN, received a US patent for genetically modified wheat. The technology included in this patent is used to insert new genetic traits into wheat such as disease and insect resistance. This type of technology is already used to develop transgenic corn, soybeans, tomatoes and other crops. This breakthrough would help re-
Search scientists develop new wheat plants with benefits for farmers, food processors and the environment.

Novartis also received a patent covering a method of protecting corn against insects, including European corn borers, which are killed when they eat corn plants containing the Bacillus thuringiensis (Bt) protein. 5596131 is the first-US patent for transgenic wheat.

Novartis Corporation received the second US patent (5610042) for genetically enhanced wheat. The patent covers a method of introducing genes for improved agronomic traits, such as insect or disease resistance into wheat plants. This method utilizes microprojectable bombardment.

Both these patents were issued on the basis of cutting-edge biotech research discoveries conducted by the former Ciba Seeds [Biotech Pat News, 11(2,3)1997, 8,7].

US patent for Gliatech technology

Gliatech Inc, Cleveland, had received a US patent No 5605938 for ADCON technology. ADCON-L and ADCON-T/N are the two anti-adhesion barrier gels developed by Gliatech for the inhibition of post-surgical scarring and adhesions.

ADCON-L is a proprietary resorbable gel that provides a physical barrier to post-operative adhesion between the spinal cord and nerve roots and the surrounding muscle and bone. ADCON-T/N has been developed to inhibit the formation of surgical adhesions following tendon and peripheral nerve surgeries.

ADCON-L and ADCON-T/N are simple to use and are applied directly to tissues and organs before wound closure where adhesions are not wanted [Biotech Pat News, 11(3) 1997,6].

Vysis given licence for lymphoma gene marker

St Jude Children's Research Hospital, Memphis, TN, has given licence to Vysis Inc, Downers Grove, IL, for developing and marketing a genetic marker associated with anaplastic large cell lymphoma.

St Jude Children's Research Hospital's mission is to discover the causes of childhood diseases and treat them appropriately. The hospital has an expertise in discovering the genetic abnormalities associated with children's diseases.

Vysis Inc would utilize their patented Fluorescence in situ hybridization technology to detect translocation of chromosomes 2 and 5, a genetic anaplastic large cell lymphoma. This translocation is not a genetically inherited chromosomal abnormality, it is an acquired genetic aberration estimated to be involved in up to 10% of all lymphoma cases. This translocation results in the fusion of the nucleophosmin gene on chromosome 5q35 to the protein kinase gene — anaplastic lymphoma kinase — on chromosome 2p23, which contributes to malignant transformation. St. Jude holds the patent to the anaplastic lymphoma kinase gene.

According to Dr A Thomas Look, MD, and Stephen Morris, MD, of the department of experimental oncology and pediatriac oncologists at St. Jude, a diagnostic for identifying the translocation also may be helpful in identifying anaplastic large cell lymphoma in patients who initially appear to have metastatic carcinoma. Because the disease can mask itself as a carcinoma, anaplastic large cell lymphoma — which is more treatable
than this carcinoma — can be difficult to identify through standard cytopathology.

"Vysis" diagnostic test, which would provide rapid and accurate results through the use of Fluorescence in situ hybridization technology, will differentiate between a carcinoma and anaplastic large cell lymphoma, thus enabling physicians to determine the most appropriate, effective and life-saving treatment for patients," said Dr Look.

Cancer mortality statistics indicate that in the United States alone, 60,000 people contracted and 24,800 people died of lymphomas in 1996. Primarily affecting children, adolescents and young adults, it is estimated that at least 70% of anaplastic large cell lymphoma cases are curable. [Biotech Pat News, 11 (4) 1997, 7].

**Osiris Therapeutics granted patent for gene therapy**

Osiris Therapeutics Inc, Baltimore, has been granted a US patent 55591625 for insertion of new genes into mesenchymal stem cell (MSCs) and their use in gene therapy. The patent licensed exclusively to Osiris, covers the novel use of human mesenchymal stem cell that can be genetically altered to express therapeutic proteins in vivo following MSC culture expansion. The gene therapy patent, together with the composition-of-matter patent assigned to Osiris in 1996 would enhance the company’s ability to commercialize its proprietary human MSC technology for clinical gene therapy applications. The company is seeking to develop cell therapy products to regenerate tissue damaged by acute injury or degenerative diseases, and biopharmaceuticals which regulate the growth and differentiation of hMSCs during the regeneration of injured or diseased tissue. The hematopoietic stem cell, which gives rise to the cells of the blood system — red cells, white cells, platelets and other blood parts — was the first stem cell to be patented. Human mesenchymal stem cells (hMSCs), now covered by the new patent, eventually be engineered to repair a gene defect or to deliver a new therapy over extended periods of time.

"The mesenchymal stem cell represents a major new target for gene therapy. Unlike a retroviral-based gene therapy system, the hMSC is not a virus, but the patients own cells which can be used to deliver a new gene", Dr Stanton L Gerson, MD, Chief of the hematology/oncology division of Case Western Reserve University, Cleveland, explained. "A patient’s hMSCs can be harvested, engineered with a new gene, and then further expanded in the laboratory. When these ‘transduced’ stem cells are infused back into the patient, they can home back to the bone marrow, or they can differentiate into the desired connective tissue. The new, fully-defined connective tissue cells, should express the new gene," Dr Gerson said, “and it is believed that they would continue to produce the new protein at clinically therapeutic levels". "The growth and differentiation of mesenchymal stem cells are fundamental mechanisms by which the body regulates the formation and regeneration of connective tissue," according to James S Burns, president and CEO of Osiris. "The ability to genetically engineer hMSCs provides a powerful approach for intervening in congenital connective tissue disorders, or for curing certain degenerative and metabolic disorders. MSCs incorporate new genes quite efficiently, and they can be further expanded during production with the therapeutic gene of choice, and subsequently reinfused into the patient." Mr Burns observed “Gene therapy opens addi-
tional clinical possibilities for Regenerative Tissue Therapy [Biotech Pat News, 11(5) 1997, 6].

**Patents on human DNA**

The increasing emphasis of genomics in the therapeutic and diagnostic R&D suggests a continuing dominant role for the pharmaceutical industry in patenting human DNA. According to a patent analysis report of patents published in 1995 that included claims for human DNA sequences, approximately 50 per cent of the 157 companies involved were American, 21 per cent Japanese and 18 per cent from Europe. Despite the huge R&D spend of the world's multinationals, they have been able to claim only 26 per cent of this patent total.

The small US biotechnology companies have almost equal impact, accounting for 24 per cent. By contrast, the relatively immature European small and medium-sized enterprise (SMEs) account for only 3 per cent of the total.

The US multinationals have a relatively small stake in these patents. Paradoxically, Merck, with its commitment to public release of human expressed sequence tags, is the exception, having more than any other company. Only 8 per cent of the total belong to US multinationals, a mere third of the US SME fraction.

The largest single category is in the area of diagnostic. This is unsurprising as any gene sequence can be used to search for mutations in a particular gene. What is certain is that only a small proportion of these patents will actually be used. These data provide evidence of a realization on the part of public sector scientists that patenting optimizes the chances of patients receiving benefits from their scientific research. US charities, universities and research institutes alike are filing for patents knowing that industry will not develop new treatment based on inventions without adequate intellectual property protection [Nature, 388 (6644) 1997, 709].

**Injectible reversible contraceptives for males**

The fertility in males can be controlled by affecting either the flow or the quality of the spermatozoa when they pass through the reproductive duct, called the vas deferens. Flow of the spermatozoa is affected either by cutting and tying the vas deferens, which in turn also destroys the spermatozoa, or by implating the occlusion device or injecting polyurethane at a high pressure, which in turn is further polymerised in situ to a solid plug by introducing an initiator. These methods affect, only indirectly, the quality of spermatozoa and have various disadvantages, like requirement of minor surgery, no or poor reliability. The direct method of affecting the quality is by injecting injectable contraceptive.

Prof S K Guha of the Centre for Biochemical Engineering (CBME), IIT, Delhi, has developed two injectible reversible contraceptives for males which can directly affect the quality of the spermatozoa to control the fertility immediately without any need of surgery. The fertility can be reversed fully at any desired time. One of the two contraceptives developed by Prof. Guha is undergoing the stage-2 clinical trials and has been granted an US Patent proving its novelty (patent filed and defended by IITD Patent Attorney). Results of clinical trials are encouraging. The other injectible reversible contraceptive is an improvement over the first one. Both the novel contraceptives can control the fertility of males immediately from the day one by affecting the quality of the spermatozoa on
injection of the contraceptive formulation. The reversibility of fertility can be achieved fully at any desired time just by injecting another formulation developed for the purpose. The flow rate and flow extent of the improved contraceptive can be controlled externally. It can also be detected externally by any non-invasive technique, such as X-rays, magnetic resonance imaging, ultrasound, etc. [FITT Forum, 3(2) 1997,9].

Process for discharge printing of silk
Discharge printing of silk is an extremely specialized technique. The methods currently in use involve steaming step as an essential step, which not only makes the overall process technically difficult, but also adds to the cost of the process due to the requirements of specific types of steamer and boiler. In addition, the steaming step may result in chemical degradation of the fabric and halos formation. The illuminant yield is reduced, and light fastness and wash fastness are generally low.

Prof. R B Chavan of the Department of Textile Technology, IIT, Delhi, has developed a new discharging agent, and a new and convenient process for discharge printing of silk, which totally eliminates the steaming step and the disadvantages associated with it. The new process comprises discharge printing of the dyed silk fabric with the new discharging agent at room temperature, which results in reduced strength loss. Hence the printed fabric obtained has better strength property. Patent for this process has been filed [FITT Forum, 3(2) 1997,9].

3D TV being patented
The Japanese company Sharp is researching 3D TV at its British laboratory, in Oxford. Patent application 2302978 reports the work of Graham Woodgate, Jonathan Harold and David Ezra. The trio want to use liquid-crystal screens, like those in laptop computers, to display 3D colour images without special spectacles.

They propose putting a vertical grid of cylindrical lenses on top of the screen. The lenses divided the image into columns, with different strips visible to the left and right eyes. The idea has been used for 3D picture postcards, but was too expensive for LCDs because it demands the red, green and blue pixels in the picture be arranged in lines instead of the triangular patterns used on existing screens.

To avoid this restriction, the Sharp researchers propose shifting triangular patterns of LCDs sideways so the pixels lie along vertical instead of horizontal lines. This requires only a small change in the mass-production process, so 3D screens should be produced at little extra cost. [New Sci, 154(2084) 1997,13].

Patent for fruit drink
A fruit drink that can be poured onto breakfast cereal instead of milk is being patented (WO 97/5787) by Jomshid Ashourian of Illinois.

The drink is made by pumping puree and juice from fresh fruit at high pressure through a nozzle, shattering the fruit cells. The mix is heated to 90°C to destroy contaminants, then bottled and heated again. The flavours available are mixes of mango and apple puree with grape and apple juice, or strawberry, blueberry and raspberry purées with the same juices. It is claimed that drinks last at least six months before separating, pour like milk and have a unique flavour, this is because when the fruit cells are broken they free pectin from the cell walls. [New Sci, 155(2090) 1997,9].
Method of cleaning waste using earthworms

Australia’s Department of Urban Services is patenting (WO 97/10190) a method of using earthworms to clean up sewage and waste contaminated with heavy metals.

The waste is mixed with paper or cardboard, shredded and aerated, producing bacteria which the worms like to eat. The dining worms absorb the heavy metals and excrete acidic castings that have cadmium levels a third lower than the original waste.

The acidic mix of soil and castings can be neutralised with lime and water, precipitating the remaining poisons. Dried castings are made into fertilising pellets for farmland [New Sci, 155(2089) 1997,11].

Patenting a computer program that helps bed allocation

The Children’s Research Institute in Washington DC is patenting a computer program (764 914) that helps it allocate beds by predicting who will live and who will die.

The task is tricky because patients can become sicker, meaning a longer stay, or their bed could be freed if they unexpectedly die.

The program draws on historical information from intensive care units all over the US to produce estimates of how patients will fare based on what they are suffering from—for example, drugs overdose, diabetes or congenital heart disease. It also factors in the quality of care that patients receive [New Sci, 155 (2091) 1997, 11].