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## Patents related to bacteria, virus and fungi - the Indian scene

The number of patent applications related to bacteria, virus and fungi filed in India has recorded substantial increase in the years 2001 and 2002. In the last issue we had presented a broader view of patent applications filed in India in the area of biotechnology. This time, we focus on patents related to microorganisms. Bacteria, fungi and virus constitute the major group of microorganisms. These microorganisms have been exploited extensively by biotechnologists. The genetic material of these microorganisms serving as raw materials, are tailored by the biotechnologists with the scissors of restriction endonucleases, stitch with ligases and converted into desirable form using sophisticated techniques of genetic engineering. The field of application of genetic engineering is broad and covers, for example, the use of fungi in bakery, wine and antibiotic industry, bacteria for the manufacture of vaccines, modification of plants/ insects genome (transgenic plants) and the like.

For over two hundred years living organisms have been excluded from patent laws; life forms were considered a 'product of nature' and not a human invention. The non patentable status of living organisms changed with the landmark decision of the Supreme Court, USA in Diamond vs. Chakraborty in 1980 when the genetically modified bacterium was granted a patent. In India such landmark decision was made on 15th January 2002 where Kolkata High Court granted patent to Dimminaco A.G. for invention involving microorganism.

In India 600 applications related to bacteria, virus and fungi have been filed since 1995 till June 2003. Of these 600 applications, 177 applications are PCT applications, 45 are convention applications and 299 are non convention applications. Two hundred and ninety four (294) applications are related to bacteria, 189 applications to virus and 21 applications to fungi.

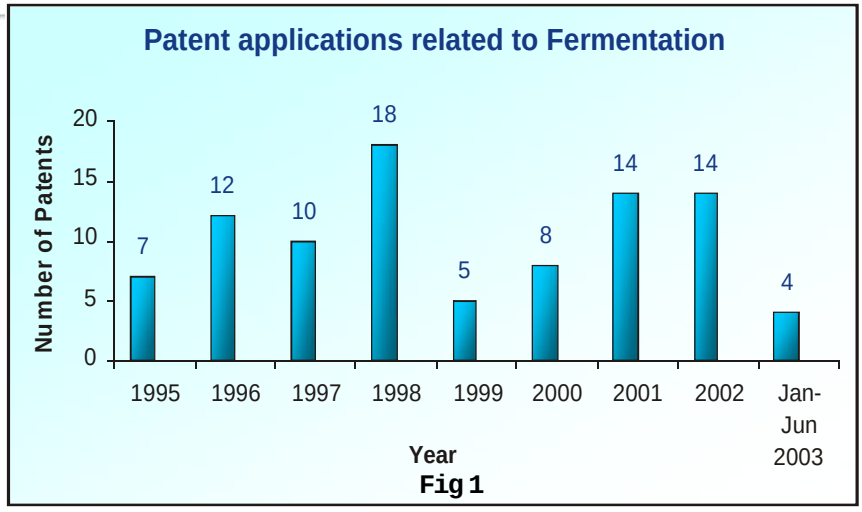

Fig 1

Of the 600 applications, 96 applications relates to fermentation (fig 1). Main applicants are CSIR (13), Gist Brocades (8), Biocon India (5), and F. Hoffmann L Roche (5).

Among the 294 applications relating to bacteria, 110 applications pertain to the compounds having antibacterial activity and processes for the preparation of the same. While 15 patent applications belong to modification of bacterial genome. 23 patent applications are related to the prophylactic use of lactic acid bacteria and 11 applications related to the genetic use of Bacillus thuringiensis. 7 patent applications have been filed for the detection of bacteia. Forty six applications speak about the industrial use of bacteria viz., production of enzymes (amylase, protease, cellulose, lactamase) and polyhydroxy-butyrates, extraction of metals, bio-

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bleaching, lignin degradation, bioremediation of petroleum products, soil nutrition and functional group transformation etc.

The maximum number of applications were filed in year 2002 (69) followed by 48 in year 2001 as shown in fig 2. Main applicants filing bacteria related applications are given below:-

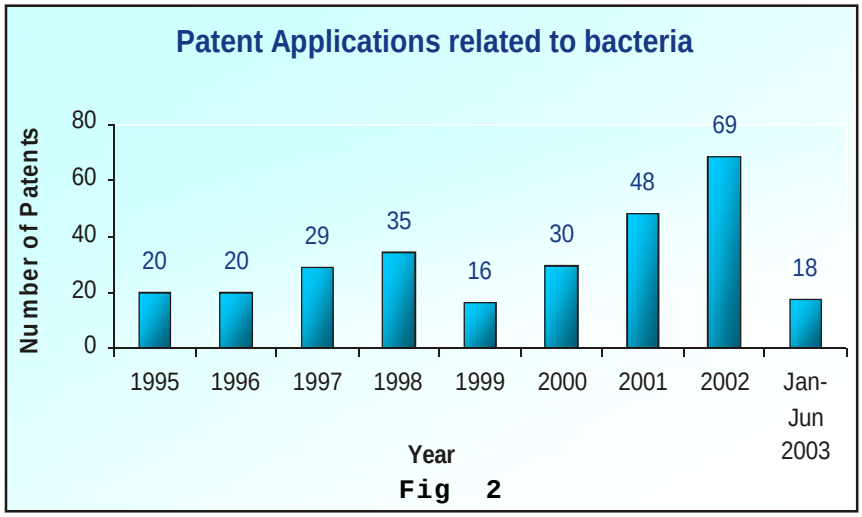

Fig 2

| S. No | Applicants | No. of patents filed till June2003 |
|---|---|---|
| 1. | CSIR | 48 |
| 2. | Societe des Produits | 14 |
| 3. | Dr. Reddys Research Foundation | 11 |
| 4. | Gist Brocades | 10 |
| 5. | Novo Nordisk | 10 |
| 6. | The Procter and Gamble | 7 |
| 7. | Astra AB | 6 |
| 8. | Biocon India | 6 |
| 9. | Ajinomoto Co | 5 |
| 10. | F Hoffmann La Roche | 5 |
| 11. | Lupin | 5 |

**Table 1.**

Virus is a unique microorganism that lies on the threshold of life. It behaves live inside the body and can be crystallized if brought out. 189 applications have been filed that are related to virus directly or indirectly. Among these, 66 applications belong to control of virus that includes herbal compositions, vaccines, antibody production using attenuated virus, viral proteins and peptides. There are 26 patent applications for methods of detection of virus. Methodologies of detection involve the use of polymerase chain reaction (PCR) using specific primers in kits, chemical and immunodetection. Six applications have been filed for virus cell lines. Virus is used as a vehicle for carrying foreign gene and transferring to the host genome. There are 7 patent applications where virus has been used as vector. These applications disclose the use of Baculovirus, retrovirus, adenovirus and vaccinia virus as vector. These applications mainly relate to hepatitis virus (38), human immunodeficiency virus (21), herpes virus (11) and rabies virus (8).

It was in the years 2001 and 2002 when the maximum number of applications for inventions involving viruses were filed as shown below (Fig. 3)

Main applicants are enlisted in Table 2 below. Indian companies seem to be very active in this area.

| S. No | Applicants | No. of patents filed till June2003 |
|---|---|---|
| 1. | Cadila Pharmaceuticals | 9 |
| 2. | Reliance Life Sciences | 9 |
| 3. | Asgrow Seed company | 8 |
| 4. | Akzo Nobel | 5 |
| 5. | NII | 5 |

**Table 2.**

Another microorganism we have mentioned above is fungi. Only 21 applications have been filed in the area of fungi. Out of these applications, 8 applications involve the methods and composition of anti fungal compounds. Rest of the applications belongs to the culture media for growth of fungi and increasing the fatty acid content. CSIR (8) and BASF Aktiengesellschaft (7) are main applicants in this field while other applicants are Novo Nordisk (2), Max Planck (1), Tata Energy Research Institute (1).

One single area which has been addressed in these applications is the area of health and it is good to see that a few Indian agencies are in the forefront. Does it forecast the emergence of the Indian biotechnology industry? Perhaps yes!

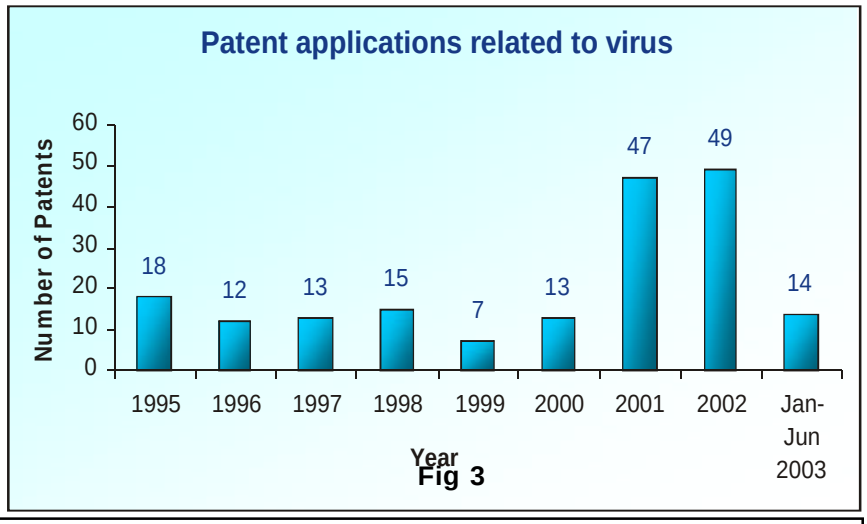

Fig 3

# No more needle pricking for drug delivery

**Case study on applicator for inhalational or mucosal delivery of drugs**

## Introduction

New medical technology invented by Hewlett Packard Development Company would eliminate the need for injections for administration of pharmaceutical compositions, particularly for peptide drugs like insulin. The method works on the principle of delivering the drug directly into the lungs through inhalation rather than injecting it like they do it at present. Although the method is not universally applicable to all illnesses, it could be one of the most important breakthroughs for the treatment of diabetes and a welcome relief for diabetic patients, especially when a majority of them have to constantly monitor their glucose levels by self-administering insulin through injections or automatic injectors attached to the body. A US patent has been granted to Hewlett Packard's technology on February 3, 2004.

## Background of the Invention

Administration of therapeutically effective doses of many medications can be difficult in some instances. For example, some drugs (particularly peptide based drugs, such as insulin) are partially or totally inactivated by the highly acidic environment of the stomach if orally ingested. Another problem is the "first pass" effect, which refers to the partial inactivation of orally ingested drugs in the liver after they have been absorbed from the gastrointestinal system and before they have exerted their full therapeutic effect. Inhalational administration has been used as an alternative route of drug delivery. Inhaled drugs can be absorbed directly through the mucous membranes and epithelium of the respiratory tract, thereby minimizing initial inactivation of bioactive substances by the liver. Inhalational delivery provides drugs directly to therapeutic sites of action (such as the lungs or the sinuses). This mode of administration has been particularly effective for the delivery of pulmonary drugs (such as asthma medications) and peptide based drugs (usually via intranasal administration), using metered dose inhalers (MDIs).

## Present Invention

The present invention addresses the problems of the prior art by devising a method and device for improving the topical or inhalational application of drugs, or mucosal delivery of drugs, by using applicators based on inkjet technologies. The applicator for inhalational or mucosal delivery of a bioactive composition uses a jet dispenser, such as a piezoelectric or thermal jet dispenser. The dispenser includes a container or reservoir for holding the bioactive composition and delivering it to a fluid ejection head for ejection through a dispenser orifice, or an array of dispenser orifices contained on one or more ejection heads. The thermal or piezoelectric jet dispenser propels precise amounts of droplets from the dispenser toward a mucosal target.

The applicator is suitable for use in a variety of ways. For example, the applicator may be intermittently used to introduce an agent into a target body orifice, such as the mouth, for administration of the bioactive agent. Alternatively, the applicator may be used to apply the agent to an area of skin for topical application of a bioactive composition, or used to transdermally introduce the bioactive agent.

Fig. 1 illustrates a mucosal or inhalational application system for administering a bioactive composition

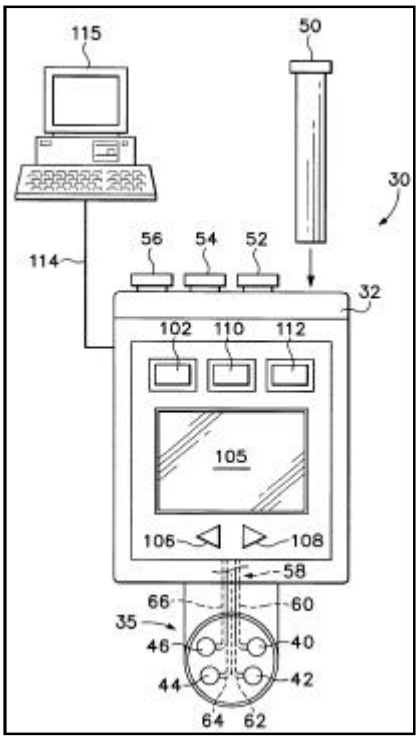


**Fig. 1**

to a subject, such as a pulmonary inhaler for the mouth of a person. The system consists of a dispenser 30 connected to one or more ejection heads, such as fluid ejection heads 40, 42, 44 and 46, by conduit fluid tubing system 58. The ejection heads are held in place within spacer 35 by intermediate spacer wall 48, and each ejection head contains at least one orifice for ejection of droplets of the bioactive composition from the dispenser. Ejection heads 40-46 may be constructed according to principles in the thermal inkjet technology, using piezoelectric ejection techniques, or other manners of fluid ejection. Indeed, the ejection of some chemicals may be benefited by a thermal ink ejection technology, in which elevated temperature can activate the agent. In contrast, other agents may chemically degrade and lose some or all bioactivity when heated in a thermal system, and such compositions may be dispensed using a piezoelectric or other non-thermal ejecting head technology.

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**No more needles .....**

The reservoirs 52-56 may be inserted into receptacles formed within main body 32 accessible from the outside of the applicator 30. Thus, reservoirs 52-56 may be removed from applicator 30 when empty and new reservoirs 52-56 inserted into applicator 30 without breaking open main body 32.

The conduit system 58 may include discrete fluid conduits, with each conduit independently connecting an individual replaceable fluid reservoir to an individual fluid ejection head. The conduits 62, 64 and 66 deliver fluid from the respective reservoirs 52, 54 and 56 to their respective associated ejection heads 42, 44 and 46. For example, replaceable fluid reservoir 52 is in fluid connection with fluid ejection head 42 via conduit 62, and replaceable fluid reservoir 56 is in fluid connection with fluid ejection head 46 via conduit 66.

The dispenser also includes a controller 110 for manually or automatically dispensing the bioactive substance from the dispenser at selected times. The controller may take the form of an actuator that is manually depressed to activate the dispenser and dispense the agent. The controller could be a programmable device or could include an audible or visible cue, such as a tone or light, to alert the subject that a dose of the bioactive composition is ready to be dispensed.

The applicator may include an input keypad, such as an alpha or alphanumeric keypad. Using keypad, a physician, nurse, pharmacist, or other health professional, or the subject 24 to which the fluid will be administered, may input variations in the amount of and types of fluids dispensed by fluid ejection heads 40-46. Applicator 30 also may include a display screen, such as liquid crystal display 105, to indicate which selections have been made using keypad 104. Alternatively, keypad may be eliminated, and the controller 100 programmed to display various selections on screen 105. Scrolling buttons 106 and 108 may allow different instructions or selections to be scrolled across, or up and down along, screen 105, including information such as desired dosages, frequency, and potential side effects.

The reservoir holding the bioactive composition may be a fixed part of the applicator or is replaceable. One or more bioactive compositions can be contained within multiple replaceable reservoirs, for example, a series of replaceable reservoirs could contain a single drug in sequentially increasing or decreasing concentrations, or a series of different, but related, drugs for the treatment of a particular condition.

The bioactive composition may be in any of the forms, liquid, gel or powder. One of the reservoirs can contain a bioactive agent in powder or other dry form and the powder can be dispensed from the container, and may in some instances be combined with a liquid en route to the target body orifice or mucosal delivery site.

The droplets of bioactive composition delivered by the applicator can be of varying sizes. The applicator is capable of dispensing very small and accurate amounts of fluids including liquids and powders. The droplets can be sized for respiratory inhalation or for delivery to bronchial airways or to nasal membranes or passages. The droplet sizes that can be dispensed by the applicator is of the order of 2 to 8 micrometers or less. The droplet size from the available inhalators is of the order of a few picolitres. The jet dispenser is also capable of dispensing differently sized droplets for distribution to multiple parts of the respiratory system, such as distributing larger droplets throughout the bronchi and smaller droplets deep into the lungs, such as to bronchioles or alveoli.

There are 30 claims out of which the first claim is reproduced:

1. An applicator for delivering a bioactive composition, comprising:

an inkjet dispenser comprising an orifice for high-speed ejection of droplets from the dispenser, the inkjet dispenser further comprising a main body;

a replaceable fluid reservoir for holding and delivering the bioactive composition to the orifice for ejection therethrough, the replaceable fluid reservoir at least partially insertable through the body; and

a body orifice spacer positioned between the dispenser orifice and a target during ejection of the bioactive composition to the target;

wherein the dispenser comprises a first orifice and a second orifice, the first orifice operable to dispense droplets of a predetermined size, the second orifice operable to dispense droplets of a predetermined size different than the size of droplets dispensed from the first orifice.

The invention incorporates certain novel features resulting in various benefits-

- The inhalers presently available are thrown away after the drug is finished. The applicator in the invention, on the other hand, contains multiple replaceable reservoirs which provides a cost-effective alternative, since only the empty reservoirs and not the entire applicator would need to be thrown.
- The multiple reservoirs in the applicator also allow multiple drug compositions to be dispensed simultaneously or

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# Cadila's combination drug loses patent battle

A patent dispute over a process patent for a combination drug held by Cadila Pharmaceuticals settled in the High Court of Ahmedabad on May 2, 2001 ultimately resulted in revocation of the process patent held by Cadila.

The plaintiff/appellant, Cadila Pharmaceuticals Ltd was granted an Indian patent in March 2000 (Patent no 183097) which claimed a novel drug delivery process for a combination medicine. The combination medicine is a penicillin-based antibiotic combined with a dose of microorganism lactobacilli, which counteracts the side effects caused by the antibiotic such as nausea, vomiting, diarrhoea etc. The combination of lactobacilli with the antibiotic normally affects the lactobacilli which loses its virality after a certain period. The plaintiff invented a novel drug delivery process which involves delivering lactobacilli in combination with a penicillin-based antibiotic, but isolated by a thin protective film which prevents the antibiotic from reacting with the lactobacilli. Such combination medicine when consumed orally, enables the lactobacilli to be effective for a long time and also counteracts the side effects of the antibiotic.

Cadila thus claimed the exclusive right to manufacture and market its innovative drug named LMX for a period of five years and the right to exclude others from manufacturing, distributing or selling a pharmaceutical product incorporating the patented process. Instacare Laboratories Pvt Ltd, the defendants were selling a similar combination drug incorporating the patented process under the names 'Hipen LB' and 'Hiponex LB'. Cadila filed an infringement suit against Instacare and applied for interim injunction restraining Instacare from manufacturing the combination drugs. The trial judge vacated the initial ex parte ad-interim injunction granted to Cadila.

Aggrieved, Cadila filed an appeal in the Gujarat High Court contending that –

- Cadila has been granted the patent for the novel process after satisfying the patent granting procedure under the law which includes advertisement for opposition from interested parties. Instacare, however, did not avail the opportunity of issuing notice of opposition before the patent was granted nor did they seek revocation of the patent after the patent was granted. Cadila emphasized that Instacare therefore had no right to defend the action for infringement and Cadila cannot be deprived of the fruits of its invention.
- Cadila's patent applications for protection in foreign countries would be affected unless the patent was protected in the home country.
- The expert appointed by the court opined that the international search report relating to a corresponding PCT application failed to reveal any valid citations relevant to the novelty and inventive merit of the claimed invention, therefore establishing the novelty and inventive merit of the present invention beyond doubt.

The defendant Instacare Laboratories contentions relied on Section 107 of the Patent Act according to which Instacare had the right to defend the infringement suit on all grounds available in Section 64 of the Act.

Section 64 of the Patent Act deals with the revocation of patents on various grounds based on the petition of any person interested or of the Central Government or as a counter-claim in a suit for infringement of the patent. According to our view, the defendants contentions relied on Section 64 (1) (e) of the Act according to which the patent must be revoked on the ground **that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13**.

The contentions were further based on the fact that combination drugs were already known to the pharmaceutical world and Cadila's claim to have invented a new process is wholly baseless and could not have been patented. Instacare also contended that they have been marketing its Hipen LB and Hiponex LB drugs since 1999 which was prior to the grant of Cadila's process patent in 2000.

The court after hearing the arguments affirmed the trial court's rejection of application for interim injunction and held that though Instacare has chosen not to serve notice of opposition under Section 25 of the Patent Act or apply for revocation of the patent under Section 64 of the Act, Section 107 of the Act empowers Instacare to defend the suit for infringement. The court also held that documentary evidence from various books indicate that the process of making combination drugs from a chemical substance (an anti-infective agent such as penicillin) and a microorganism (such as lactobacilli) and isolating one of the ingredients by giving it a coating of protective film are both known and well accepted process. The process for making

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# Litigation Watch

The US Court of Appeals for the federal court has reversed the district court's judgment that intertool failed to satisfy the written description requirement. The court emphasized the 'complete and exacting' detail of the claimed structure and the preamble's lack of any additional structure that the specification had emphasized as important. Thus the preamble phrase was not considered as a limitation.

**Patent World, July/August 2004**

Microsoft responded to the European Commission's anticompetitive ruling against the company by filing two requests at the Court of First Instance in Luxembourg. The first requests a suspension of the Commission's remedies, arguing that they harm software developers, website developers as well as Microsoft. The second filing appeals against the Commission's ruling arguing that the decision creates an untested new law. It says that once IPRs are lost they cannot be recovered and hence a stay is necessary.

**Patent World, July/August 2004**

L.G.Phillips LCD, the world's second biggest maker of flat screens for laptops, computer monitors and televisions, has filed patent infringement lawsuit against US and Taiwanese rivals ViewSonic Corp and Tatung. L.G.Phillips LCD is a joint venture between LG Electronics and Phillips Electronics. The Lawsuit is the latest in a series of patent infringement suits in Asia that reflect a sharp competition in the electronics market.

**The Times of India, June 3, 2004**

Rambus Inc, a computer-memory chip designer, withdrew parts of its patent infringement claim against Infineon Technologies AG, Europe's second-largest semiconductor maker, and is pressing ahead with other parts of the suit. Rambus is suing Infineon, Micron Technology Inc. and Hynix Semiconductor Inc. in Germany and the US, claiming they infringed patents after refusing to sign licensing agreements.

**Business Line, July 21,2004**

Luxury Jeweller Tiffany & Co has sued eBay Inc, claiming the online auctioneer has contributed to violations of the Tiffany trademark by letting counterfeit items be sold on its website. A study in certain pieces of 'Tiffany' jewelry sold on eBay this year showed that 73% of the jewellery was counterfeit. The lawsuit asks the eBay be stopped from listing any Tiffany merchandise that is not genuine and for eBay to account for profits it made on the counterfeit Tiffany merchandise or else pay up to $1 million for each type of fake Tiffany merchandise sold on the website.

**The Economic Times, June 23, 2004**

Data center gear makers Radware and F5 Networks battle over patents again. Radware, which makes networking products that balance traffic between servers, has filed a lawsuit against competitor F5 Networks for infringing on a April 2004 patent. The patent is for technology that determines the proximity of devices within a network when making load-balancing decisions. Radware is seeking an undisclosed amount of monetary damages as well as permanent injunctive relief.

**The Financial Express, July 23, 2004**

The world's biggest drugmaker, Pfizer Inc, is taking legal action against dozens of online pharmacies which it alleges are selling counterfeit versions of the erectile dysfunction drug Viagra. The company has launched an advertising campaign to educate the public about what it calls illegitimate Websites.

**The Tribune, August 5, 2004**

Mumbai based Sun Pharma has been sued by Medimmune Oncology for a patent infringement by Sun's filing in the US market for generic version of cancer-related drug Ethyol (amifostine). Sun Pharma had filed a Drug master File for generic Ethyol earlier this year. The drug is reported to have clocked revenues of $94 million in 2003 in the US and its patens expire in July 2012/December 2017. The patent-challenge route adopted by Sun Pharma may be a 'jackpot' if they win the case.

**Business line, August 22, 2004**

International sports apparel company Lacoste had filed a lawsuit alleging that the Chennai-based exporter, Global Impex India, used its registered trademark "Lacoste" and copyright logo "Crocodile" to promote its goods and to confuse the customer in believing that the product was emanating from the international company. The Delhi High court has restrained the Indian export firm from carrying out its business which was adversely affecting Lacoste's reputation.

**Asian Age, August 21, 2004**

GlaxoSmithKline, Europe's largest drugmaker, gave up its fight to protect a key ingredient in its leading anti-diabetes medicine sold in China, the second reverse in a month for a Western drug company in the $10-billion market. Glaxo won't proceed with a counter-suit against Chinese drugmakers that challenged its patent for rosiglitazone, one of three patented ingredients in Avandia. China wants to cut the price of Western medicines and make them widely available to Chinese patients.

**The Economic Times, August 19, 2004**

# Patents for Opposition

The following patent applications have been accepted by the Patent Office and published in the Gazette of India. These can now be opposed by filing opposition applications within a period of four months from the dates given. Six digit numbers allotted after acceptance by the Patent Office are given before the applicant names and patent application numbers given in brackets. Names of the branches of the Patent Office are denoted in the application number, e.g. 'Bom' for Bombay branch. An opposition application should be submitted at the appropriate office where the concerned application was originally filed.

**May 22, 2004**

| | |
|---|---|
| 192791. Jophnson And Johnson Medical Inc, United States (1209/CAL/97) | Bioabsorbable medical device from oxidized polysaccharides |
| 192792. The Trustees Of Princeton University U S A (642/CAL/94) | A process for preparing a composite consisting of a supporting substrate with a photochemically active multi layered film |
| 192793. Copeland Corporation SA (342/CAL/01) | A scroll type machine |
| 192794. Owens Corning Canada Inc Canada (801/CAL/97) | A machine for making chopped strand mat and a process for making chopped strand mat |
| 192795. Kone Oy Finland (2032/CAL/97) | Sliding safety gear |
| 192796. Kabushiki Kaisha Mihama Seisakusho Japan (1802/CAL/97) | An improved clamping band |
| 192797. LG Electronics Inc Korea (1561/CAL/97) | Apparatus for supplying cold air an refrigerators |
| 192798. Fianara Internation B V The Netherland (84/CAL/01) | Coffee machine |
| 192799. Steel Authority Of India Ltd India (1594/CAL/97) | A low cost process for producting low sulphur and phosphorus content ductile iron |
| 192800. Kawasaki Thermal Engineering Co Ltd Japan (1224/CAL/97) | A nitrogen oxide reducing apparatus in oil fired absorption refrigerating apparatus |
| 192801. Steel Authority Of India Limited New Delhi (1185/DEL/95) | A completely cement free refractory castable composition (ZCC) and a process of preparing the composition |
| 192802. Council Of Scientific And Industrial Research New Delhi ( 437/DEL/95) | A process for the synthesis of 3s 2 substituted 1 2 3 4 tetrahydro 9h pyrido 3 4 b indole 3 carboxylic acids useful as potential anti cholecystokinin agents |
| 192803. Steel Authority Of India Ltd New Delhi (1279/DEL/95) | A shutter device for actuating a gamma ray source of fail safe pushing operation in coke oven |
| 192804. Saitec S R L An Italian Company Italy (1314/DEL/95) | Apparatus for preparing solid forms with controlled release of active ingredients and method carried out therein |
| 192805. De La Rue Glori Switzerland (746/DEL/95) | A suction roller |
| 192806. LG Electronics Inc Korea (1899/DEL/95) | Apparatus for packing content of a microwave |
| 192807. Esco Corporation United States Of America (1571/DEL/95) | A lock pin fort coupling a point to an adapter to form an excavating tooth |
| 192808. Rameshwar Dayal Srivastava India (1423/DEL/95 ) | Adjustable R.C.C. door frame |
| 192809. Intel Corporation United States Of America (1876/DEL/95) | An encoding system |

# Domestic News

Mysore silk is the next 'indegenous' product in line for a Geographical Indications (GI) tag. The GI registration accords unique identity to this silk, its source and processessing as a 'traditional knowledge' product. Mysore silk will be the ninth such TK product that has a unique geographic origin. Eight products which have been granted GI include Darjeeling tea, Pochampalli sarees, Salem fabric, Goan feni, Solapur fabric, Pavitra modaram (ring) from Payyanur kerela, Chanderi saree and Aranmul kannadi (mirror) from Kerela.

**Deccan Herald, August 18, 2004**

Counterfeits and passoffs continue to trouble the FMGC industry, with the Government estimated to lose close to Rs 900 crore per annum in unpaid excise duty, sales tax and other levies. FICCI informed that a raid conducted by the Delhi Police in collaboration with the Chamber's Brand Protection Committee (BPC) during the weekend in the Capital uncovered Rs 5 crore worth of machinery and packaging materials being used to manufacture counterfeit products. Holographic plates of Sunsilk, Clinic Plus, Chik Shampoo and Ariel detergent have been seized along with large quantities of packing material of many popular brands.

**Business line, August 18, 2004**

The Economic Offences Wing (EOW) claims to have seized pirated software and VCDs/DVDs/MP3 worth Rs 7.15 crore during raids in New Delhi, (Farsh Bazar, Nehru Place, Palika Bazar and Shalimar Bagh) over the past two weeks.

**The Hindustan Times, August 6, 2004**

Karnal-based Directorate of Wheat Research (DWR) has been granted a process patent to use a chemical agent for imparting sterility in the crop. The patent has been granted by the Indian Patent Office for a process

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| | |
|---|---|
| 192810. Laboratories Cusi S A Spain (2433/DEL/95) | A container for pharmaceutical substances and a process for assembling thereof |
| 192811. Maytag Corporation USA (1635/DEL/95) | A laundry device |
| 192812. Sony Corporation Japan (2165/DEL/95) | A transmitting receiving apparatus |
| 192813. Council Of Scientific And Industrial Research New Delhi (1794/DEL/95) | A device for the measurement of thoracic gas volume for diagnosis of lung diseases |
| 192814. Steel Authority Of India Limited New Delhi (1077/DEL/95) | Process of manufacturing coiled spring |
| 192815. Steel Authority Of India Limited New Delhi (2234/DEL/95) | An improved burner operable from lean gases and low viscous oils supplied simultaneously or singly |
| 192816. Council Of Scientific And Industrial Research New Delhi (503/DEL/95) | An improved process for the preparation of para di alkyl benzene |
| 192817. Alcan International Ltd Canada (1312/DEL/95) | A process for manufacturing a metal strip and an apparatus for the same |
| 192818. Arun Kumar Delhi (1048/DEL/95) | A door viewer mounted in a door |
| 192819. Buehler Ag Switzerland (1446/DEL/95) | Micro metering device |
| 192820. Allied Tube And Conduit Corporation United States Of America (838/DEL/95) | Coating apparatus and method for applying a coating to a length of horizontally oriented metal tubing |
| 192821. Council Of Scientific And Industrial Research New Delhi (411/DEL/01) | An improved process for the production of fructiooligosaccharides using culture both of aureobasidium pullulans |
| 192822. Council Of Scientific And Industrial Research New Delhi (1206/DEL/01) | A process for the preparation of 1 arylaikyl 5 oxo proline carboxamide aryalkyl 5 oxo proline carboxamide useful as thrombin inhibitors |
| 192823. Council Of Scientific And Industrial Research New Delhi (495/DEL/99) | An improved process for the preparation of a hydrophilic bone inductive protein |
| 192824.Council Of Scientific And Industrial Research New Delhi (1355/DEL/99) | An improved process for the preparation of soy protein hydrolysate from legumes |
| 192825. Council Of Scientific And Industrial Research New Delhi (1124/DEL/00) | A process for the production of 6 0 beta d glucopyranosyl oxy benzene ethylamine |
| 192826. Council Of Scientific And Industrial Research New Delhi (278/DEL/00) | High yielding substrate for cultivation of mushrooms using coir waste |
| 192827. Council Of Scientific And Industrial Research New Delhi (299/DEL/00) | A process for the preparation of 3 sulfanyl cyclic ketones |
| 192828. Council Of Scientific And Industrial Research New Delhi (407/DEL/01) | A process for the preparation of pyridine |
| 192829. Council Of Scientific And Industrial Research New Delhi (3322/DEL/98) | A process for preparation of an artificial promoter |
| 192830. Council Of Scientific And Industrial Research New Delhi (2713/DEL/98) | A process for the preparation of a fungicide |
| 192831. Council Of Scientific And Industrial Research New Delhi (1772/DEL/98) | A synergistic composition of polymeric blend useful for preparation of biodegradable polymer device |
| 192832. Council Of Scientific And Industrial Research New Delhi (3692/DEL/98) | A process for the preparation of a composition useful for increasing shelf life of fruits and vegetables |
| 192833. Council Of Scientific And Industrial Research New Delhi (730/DEL/00) | An improved process for the isolation of bixin dye from bixa orellana (anneto) |
| 192834. Council Of Scientific And Industrial Research New Delhi (1162/DEL/00) | A process for preparation of a composition useful for effective protection against the ultraviolet uv radiation |
| 192835. Council Of Scientific And Industrial Research New Delhi (358/DEL/00) | A method for the preparation of anti microbial composition useful in the treatment of drug resistant bacterial infections |

*Contd from...7*

**Domestic News .....**

of making the chemical used in hybrid wheat seed production leading to a significant step towards increasing wheat output by around 20% to over 100 million tones. The corresponding US patent application is also pending in the USPTO since March 2002.

**Business line, August 30, 2004**

The Union Cabinet has referred the Patents Amendment Bill to a group of ministers to study the implications of some of the contentious issues in the third Patents Amendment Bill before approving it. The government is seeking amendments to the Patents Act to fulfill India's obligations under the commitment to the WTO of having in place product patents by 2005. The group of ministers on Patents includes Defence Minister Shri P Mukherjee, Health Minister Shri A Ramdoss, Human Resources Minister Shri A Singh, Commerce and Industry Minister Shri Kamal Nath, Science and Technology Minister Shri Kapil Sibbal, Chemical and Fertilizer Minister Shri Ram Bilas Paswan and Agriculture Minister Shri Sharad Pawar.

**Central Chronicle, August 27, 2004**

Music piracy level in India is estimated at over 25%, according to a recent study by Pricewaterhouse-Coopers (PwC). Among Asian countries, Hong Kong, the Philippines, Taiwan and Thailand are at India's level. Piracy in Indonesia, Malaysia and Pakistan is much higher at over 50%. China tops the list in the region with over 90% piracy rate.

**The Financial Express, August 26, 2004**

The estimated loss to the Indian film industry due to pirated video cassettes and discs per year was Rs 400 crore. Information in this regard was provided to Rajya Sabha by FICCI. The Government has been receiving from time to time

***Contd on...9***

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|---|---|
| 192836. Council Of Scientific And Industrial Research New Delhi (727/DEL/00) | A process for the preparation of (2r,3s,22s,23s)-2,3,22,23-tetracetoxy b homo 7 oxastigmastan 6 one |
| 192837. Council Of Scientific And Industrial Research New Delhi (129/DEL/00) | An improved process for preparation of white pepper |
| 192838. Council Of Scientific And Industrial Research New Delhi (93/DEL/00) | An improved process for the preparation of a alpha formyl aryl acetates |
| 192839. Council Of Scientific And Industrial Research New Delhi (267/DEL/0)0 | An improved culture medium for haematococcus useful for enhanced carotenoid production by heamatococcus cyst |
| 192840. Council Of Scientific And Industrial Research New Delhi (379/DEL/0)0 | A process for the isolation of trans tetracos 15 enoic acid having hepatoprotective activity from indigofera sp |
| 192841. Council Of Scientific And Industrial Research New Delhi (570/DEL/9)9 | An improved process for the preparation of 2 aryl propionic acid |
| 192842. Council Of Scientific And Industrial Research New Delhi (1195/DEL/99) | A process for preparation of odourless soybean oil |
| 192843. Council Of Scientific And Industrial Research New Delhi (540/DEL/99) | A method for simultaneous recovery of cephalosporin c and deacetyl cephalosporin c from fermentation both |
| 192844. Council Of Scientific And Industrial Research New Delhi (1561/DEL/99) | An improved process for the preparation of cycloalkylphenols |
| 192845. Council Of Scientific And Industrial Research New Delhi (413/DEL/01) | A process for the preparation of intracellular phenyalalanine ammonia-lyase enzyme |
| 192846. Council Of Scientific And Industrial Research New Delhi (370/DEL/01) | An improved process for preparation of paste from onion and garlic bulbs having longer shelf stability |
| 192847. Council Of Scientific And Industrial Research New Delhi (41/DEL/01) | An improved process for the preparation of food grade sodium benzoate |
| 192848. Council Of Scientific And Industrial Research New Delhi (166/DEL/0)1 | A process for the preparation of novel phyto-ecdysteroids |
| 192849. Council Of Scientific And Industrial Research New Delhi (92/DEL/01) | A process for the preparation of a novel cis cis 3 hydroxy 5 methylcarbonyloxy cyclohexylacetate useful as an intermediate for 6 hydroxymethyl 4 tert butyldimethylsilyloxy 4 4r 6s tetra hydro 2h 2 pyranone |
| 192850. Council Of Scientific And Industrial Research New Delhi (474/DEL/01) | An improved process for the preparation of 2 methyl 1 4 naphthoquinone |
| 192851. Council Of Scientific And Industrial Research New Delhi (94/DEL/01) | A process for the preparation of a formulation useful for the insect free storage of cereals |
| 192852. Council Of Scientific And Industrial Research New Delhi (0047/DEL/00) | A process for the preparation of novel 4 alkyl 7 o acetamid 2 yl 2h 1 benzopyran 2 ones |
| 192853. Council Of Scientific And Industrial Research New Delhi (0048/DEL/01) | A process for the preparation of alkyl aryl 3 amino 3 glycosylated propanoates and corresponding propanoic acids |
| 192854.Council Of Scientific And Industrial Research New Delhi (412/DEL/01) | A process for the production of verbenol |
| 192855. Council Of Scientific And Industrial Research New Delhi (414/DEL/01) | A process for the preparation of purified lecithin from crude rice bran oil |
| 192856. Council Of Scientific And Industrial Research New Delhi (787/DEL/97) | A process for the preparation of an improved coating useful for coating the surfaces of stainless steel and super alloys |
| 192857. Council Of Scientific And Industrial Research New Delhi (371/DEL/00) | A process for the preparation of 4 isobutylacetophene 4 ibap |
| 192858. Council Of Scientific And Industrial Research New Delhi (153/DE/00) | A process for the preparation of 4 aryl 2 6 dimethyl 3 karboethoxy 5 carbomethoxy 1 4 dihydropyridines useful as therapeutic agents |

*Contd from...8*

**Domestic News .....**

representatives from the film industry vis-à-vis the need for strict action against piracy. The responsibility of dealing with offences under the Copyright Act rests with the police authorities of the state government and the Union territory Administration.

**The Assam Tribune, August 18, 2004**

India and US signed a letter of intent to work together to bring out 'drought and saline resistant high-yielding crop varieties through biotechnology, that will have more nutritious contents like iron and vitamins. After signing the agreement the Union Minister for Science and Technology, Mr. Kapil Sibal, told that the two sides would not take any matter involving issues of intellectual property rights and the farmers will be free to use the seeds.

**The Tribune, June 30, 2004**

Thanks to a technique patented by a young Indian researcher Ajai K Sonkar, India may replace Japan, Australia, America and several island countries as the home for the world's largest culture pearls. Dr. Sonkar has developed a special technique of implantation using the Pinctada margaritifera also known as the black lip oyster to produce pearls. The results of the first batch were stunning wherein of the 1000 oysters that were implanted, 905 produced pearls and none of them died.

**Hindustan Times, July 24, 2004**

A scientist from the National Geophysical Research Laboratory in Hyderabad, Dr. Vishnubhotla Chakravarthi, has obtained a US patent to develop software that will help make accurate predictions of the distance at which hydrocarbons (petrol, natural gas) are available under the earth. The software would be a great help in oil and gas exploration as the margin of error in the method is just 4% as compared to 34% by conventional methods.

**Hindustan Times, July 19, 2004.**

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| 192859. Steel Authority Of India Limited Research And Development Centre For Iron And Steel New Delhi (576/DEL/96) | An improved semi dry gunning mix for repairing the eroded refractory linings of steel teeming ladles and a method of preparing the same |
| 192860. Steel Authority Of India Limited Research And Development Centre For Iron And Steel New Delhi (66/DEL/96) | An improved method for cast iron ingot moulds |
| 192861. Ranbaxy Laboratories Ltd India (630/DEL/00) | An improved process for the isolation of lovastatin |
| 192862. Ranbaxy Laboratories Ltd India (1483/DEL/99) | A process for the preparation of 3 ethoxy 4 ethoxycarbonyl phenyl acetic acid |
| 192863. Ranbaxy Laboratories Ltd India (1144/DEL/01) | Process for the synthesis of novel isobenzofurans |
| 192864. Ranbaxy Laboratories Ltd India (856/DEL/00) | A process for the preparation of controlled release formulations of ofloxacin |
| 192865. Bharat Heavy Electricals Ltd India (114/DEL/96) | An improved impeller for centrifugall compressor |
| 192866. Ambika Prasad And Trinetra New Delhi (730/DEL/96) | AC DC electro magnet device as constitutional remedy for promotion of health |
| 192867. Fil Terwerk Mann Hummel Gmbh Germany (195/DEL/96) | A fluid powered centrifugal cleaner device |
| 192868. Sony Corporation Japan (281/DEL/96) | Liquid crystal display device |
| 192869. I M A Industria Macchine Automatiche S P A Italy (749/DEL/96) | A method of manufacturing a filter bag by pleating and folding an elongatedly shaped tubular blank of filter paper |
| 192870. Smithkline Beecham P L C England (3258/DEL/98) | A process for preparing 5 4 2 n methyl n 2 pyridyl amino ethoxy benzyl 2 4 thiazolidinedione or a tautomeric form thereof or a salt thereof or a solvate thereof |
| **May 29, 2004** | |
| 192871. Praxair Technology Inc Brazil (789/DEL/01) | A process for preparing an improved sugar product |
| 192872. Indian Council Of Medical Research India (179/DEL/01) | A process for the production of mosquitocidal compound |
| 192873. Squires Meryl Joan USA (503/DEL/01) | A process for preparing a synergistic herbal pharmaceutical composition |
| 192874. Bayer Corporation United States Of America (601/DEL/97) | A process for the preparation of synthetic bikunin |
| 192875. All India Institute Of Medical Science India (822/DEL/97) | A process of coating elisa plates with a novel antigen mixture of indian subtype c HIV 1 gp 120/gp 41 and HIV 2 gp 36 envelop components and HIV 1 virus lysate |
| 192876. The Chief Controller Research Development Ministry Of Defence India (602/DEL/00) | A process for preparation of soluble fibre enriched baked product for reducing blood sugar and blood cholesterol |
| 192877. Hovione Inter Ltd Switzerland (555/DEL/99) | A process for the preparation of 4 des dimethylamino tetracyclines |
| 192878. Tencel Limited England (487/DEL/94) | Apparatus for the communication of sheets of wood pulp feedstock into platelets of said feedstock |
| 192879. Centre For Development Of Telematics India (1696/DEL/94) | A forward error correction decoder device for correcting upto two errors and detecting three errors using modified rate 7 8 bch 128 112 coding scheme in a satellite communication system |
| 192880. K G M Associates India (88/DEL/96) | A letter box |
| 192881. Nippon Shokubai Co Ltd Japan (346/MAS/96) | A process for manufacturing a detergent builder |
| 192882. Basf Aktiengesellschaft Germany (486/MAS/96) | A process for the preparation of the reactive dye |

## International News

The New Zealand Court of Appeal has upheld a ruling by the High Court that claims for medical treatment for human beings are not patentable. The Court of Appeal decided that "a claim to a method of medical treatment did not satisfy the definition of 'invention' in the New Zealand Patents Act." The New Zealand Government is also examining the issue as part of a three-stage review of the Patents Act 1953.

**Patent World, July/August 2004**

Biotechnology and pharmaceutical patenting has finally leveled off after significant growth throughout the 1990s according to the latest *Biotechnology Innovation* Report by Finnegan Henderson, released at BIO 2004. The report also found that the 'Biotech patent ownership' has shifted further in favour of the private sector and away from the ownership by universities and the US Government."

**Patent World, July/August 2004**

Intellectual Property Rights are a key element of US trade policy and a major obstacle for Russia to overcome if it is to join the World Trade Organization (WTO). Piracy of software and video is thought to rob Russia's budget of between $1 billion to $4 billion year, according to the figures from the Trade and Economic Development Ministry's trade inspectorate. Russia is moving towards a trade deal with European Union that would bring it close to joining the WTO. Even if the EU and Russia agree accession terms, the United States and others still have to give their approval.

**Hindustan Times, June 3, 2004**

Drug company Eli Lilly's research and development centre is located in Singapore inspite of the fact that the company has many Indians as staff members. Singapore has marched ahead of India by not just creating a conducive environment, but also by establishing the

***Contd on...11***

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|---|---|
| 192883. Central Sericultural Research And Training Institute India (1419/MAS/97) | A process for the preparation of a biofungicide |
| 192884. Katsu Manufacturing Co Ltd Japan (1608/MAS/96) | An agitation apparatus for agitating pellets of synthetic resin |
| 192885. Haraeus Electro Nite International Nv Belgium (314/MAS/96) | A measuring cell to measure an electro chemical activity |
| 192886. Ciba Specialty Chemicals Holdings Inc Switzerland (293/MAS/96) | Azo dye mixture |
| 192887. Natco Pharma Limited India (876/MAS/01) | An improved process for the preparation of curcumin |
| 192888. National Gypsum Properties LIC, USA (250/MAS/01) | A fiber board and a method of producing the same |
| 192889. Surendra Kumar Sood India (410/MAS/01) | A process for the preparation of deep fat fried potato chips |
| 192890. F Hoffmann La Roche Ag Switzerland (153/MAS/01) | A process for the preparation of a 4 5 diamino shikimic acid derivative |
| 192891. Dow Global Technologies Inc USA (1572/MAS/95) | A process for preparing a supported catalyst component |
| 192892. Aluminium Pechiney France (1694/MAS/95) | A process for preparing iron-free supersaturated sodium-aluminate solutions |
| 192893. Andritz Oy Finland (142/MAS/96) | A method of producing black liquor from a pulping process |
| 192894. Palitex Project Company Gmbh Germany (288/MAS/96) | A textile machine |
| 192895. Mudalthirumaligai Srinivasa Nandakumar India (427/MAS/96) | A method of and an apparatus for continuous manufacture of steel |
| 192896. Bottari Marco Italy (758/MAS/96) | A yarn center made from molded thermoplastic resin |
| 192897. Shell Internationale Research The Netherlands (770/MAS/96) | A process for the preparation of a lubricating base oil |
| 192898. Luxfer Group Limited United Kingdom (188/MAS/96) | A method of preparing a magnesium base alloy for high pressure die casting |
| 192899. F Hoffmann La Roche Ag Switzerland (763/MAS/00) | A process for preparing a pharmaceutical composition having enhanced bioavailability |
| 192900. American Home Products Corporation USA (560/MAS/97) | A method of manufacturing pharmaceutical capsule and an apparatus thereof |
| 192901. Maumee Research And Engineering Incorporated USA (1428/MAS/95) | A process for treating metal oxide fines to recover elemental iron |
| 192902. Mobil Oil Corporation United States Of America (1340/MAS/95) | A process for the polymerization of cyclic ether monomers for the production of polyoxyalkylene polymer |
| 192903. C S R Prabhu India (1334/MAS/95) | A process for the preparation of herbal biodegradable liquid fire extinguisher and imparter of fire burn resistance |
| 192904. Elf Atochem S.A. France (1153/MAS/95) | Process for the purification of difluoromethane |
| 192905. Mitsubishi Denki Kabushiki Kaisha Japan (1077/MAS/95) | A stator of a magnet type rotating machine |
| 192906. S K Corporation Korea (1040/MAS/95) | Process for separating the high boiling fraction from a crude butyne diol solution |
| 192907. Robert Bosch Gmbh Germany (895/MAS/95) | A fuel injection valve for internal combustion engines |
| 192908. Henkel Corporation USA (859/MAS/95) | A coated metal article and a method of producing the same |
| 192909. Toshiba Lighting And Technology Corporation Japan (798/MAS/95) | A compact fluorescent lamp unit |
| 192910. Indian Institute Of Science Bangalore India (788/MAS/95) | A process of preparing molybdenum disilicide ($MoSi_2$) |

*Contd from...10*

**International News .....**

necessary infrastructure to 'entice' research-oriented companies to flock to Singapore. A primary reason why Singapore is chosen over India is because they protect IPRs and there exists clarity in regulation, besides other financial benefits. Besides companies such as Pfizer, Schering Plough, Wyeth and Siemens that have operation in Singapore, local and international biotech companies looking at drug discovery are also making a beeline to the city.

**Business Line, June 29, 2004**

Shaolin Temple, the home of Kung Fu, has extended its self defense strategy from martial arts to trademark protection. Monks at the 1,500-year-old Buddhist temple in Henan province plan to register the Shaolin name in more than 80 countries to prevent what they claim is its improper use to promote cigarettes, beer, lingerie and bogus schools.

**Hindustan Times, July 7, 2004**

Microsoft has been awarded US patent 6,754,472, entitled: Method and apparatus for transmitting power and data using the human body. Microsoft envisages using the human skin's conductive properties to link a host of electronic devices around the body, from pagers to personal data assistants to mobile phones and microphones. The technology could usher in a new class of portable and wearable electronic gizmos such as earrings that deliver sounds sent from a phone worn on the belt, and special spectacles with screens that flash up accompanying images and video footage. The patent says the body could generate the power needed to run its various attached devices in a similar way to self-winding watches. Most futuristically, it proposes that an area of skin could even act as a keypad, whereby you could type by tapping on your forearm.

**Hindustan Times, July 7, 2004**

Mylan laboratories acquired King Pharmaceuticals Inc for about $4

***Contd on...12***

*Contd from...4*

**No more needles .....**

sequentially. For example, a corticosteroid contained in one of the reservoirs can be administered to a subject having stable reactive airway disease and if symptoms persist, then the beta-agonist contained in another reservoir also can be delivered. The multiple reservoirs thus provide the flexibility to dispense drug compositions based on changing clinical circumstances.

- The applicator can be used for intranasal or inhalation administration of both simple and complex drug regimens to treat various diseases, eg., vasopressin can be administered intranasally to treat central diabetes insipidus, and opiods or benzodiazeprins can be delivered by pulmonary inhalation for treatment of anxiety in lung cancer patients.
- The controller in the applicator can be programmed to adjust dosage of an administered drug depending on the clinical circumstances. The dosage can be adjusted for a particular time period, or based on an event that require a dosage modification (eg., an adverse drug reaction that requires reduction of drug administration). The invention thus enables complex drug administration.

*Contd from...5*

**Cadila's combination .....**

a combination drug of penicillin (anti-infective agent) and lactobacilli (microorganism) may have been patented for the first time but what is patented is the process and not the combination drug itself. Thus, prima facie, the process evolved by Cadila is not found to be patentable and Instacare cannot be restrained from using the process for its products and marketing them. The court was also of the opinion that the trial judge in vacating the ex parte ad interim injunction and rejecting the application for interim injunction was justified.

*Despite so much dispute in India for this process patent, Cadila Pharmaceuticals were successful in getting their process patent granted by the British Patent Office and United States Patent and Trademark Office in the year 2001 (PFC's finding). Cadila Pharmaceuticals has also filed a complaint in the Supreme Court seeking action against the patent infringement. Obtaining, maintaining and enforcing patents are not simple activities. In this case Cadila may use the wisdom of British and the US patent offices to push its case in the Supreme Court . It would be an interesting battle to watch as it may involve many technical brains to establish/de establish the claims of Cadila.*

*Contd from...11*

**International News .....**

billion, adding a few branded drugs to Mylan's generic-drug offerings. The deal would help Mylan make the jump from copy-cat drugs to more profitable patent-protected drugs, a transition that almost every generic drug company aims to make.

**The Economic Times, July 27, 2004**

Forgent Network Inc, a modest software company, has found goldmine in patents. Forgent has been hiring lawyers to extract revenue from the company's store of old patents. The company has already reaped nearly $50 million by claiming that one of its patents cover JEPG, the popular standard for digital images. The company is now demanding payment for a patent it says underlies the digital-recorder technology.

**The Financial Express, July 30, 2004**

Pfizer Inc failed to get a restraining order blocking Ivax Corp from selling a copy of its Neurontin seizure medicine, which generated $2.7 billion in sales last year. Ivax is selling a tablet form of gobapentin, the main ingredient of Neurontin. Since Pfizer sells Neurontin in the capsule form, doctors have to specify that Ivax's version is acceptable before pharmacists can substitute the Ivax drug when filling Neurontin prescriptions. Pfizer will continue with other legal options.

**Business line, August 22, 2004**

**Please send us questions and topics you would like to see in the coming issues**

***NEXT ISSUE***

- **Case Study**
- **Case Law**
- **Patents for Opposition**

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