

REGULATORY UPDATE

Bio-piracy: India wins case against 15 patents

The European Patent Office (EPO) has rejected 15 patent applications of various international companies during the past one year after it found they had used India's traditional medicinal knowledge to prepare certain products.

The action was taken after the government entered into an access agreement with EPO in February last year to share India's traditional medicinal knowledge and prevent the practice of foreign companies taking patent on Indian systems of medicine.

"We identified 36 cases of bio-piracy and took them with EPO. Fifteen cases have been already rejected by the EPO.

We expect another 21 to be rejected soon," V K Gupta, Director of Traditional Knowledge Digital Library (TKDL), a project to conserve and share the knowledge on the Indian medicine systems, said. The government has embarked upon digitalising the traditional knowledge under TKDL project.

India has also joined hands with the US and UK to prevent the practice of international companies taking patent on Indian systems of medicine.

When the patent is awarded, the examiner goes through the available database on similar formulations.

The government started the TKDL project in 2001. About two lakh medical formulations have been digitalised under it. About 2000 patents are wrongfully awarded annually on certain formulations which are already there in the Indian medicinal systems.

A study carried out by TKDL has found a sharp decline on filing of patent applications concerning Indian system of medicines, particularly in the generic group on medicinal plants at EPO

NEW APPROVALS

Lumizyme (alglucosidase alfa)

Company: Genzyme Corporation
Date of Approval: May 24, 2010

Treatment for: Pompe disease
Lumizyme (alglucosidase alfa) is a lysosomal glycogen-specific enzyme indicated for patients 8 years and older with late (non-infantile) onset Pompe disease.

Zymaxid (gatifloxacin) Ophthalmic Solution

Company: Allergan, Inc.
Date of Approval: May 18, 2010
Treatment for: Bacterial Conjunctivitis
Zymaxid (gatifloxacin ophthalmic) is a fluoroquinolone anti-infective indicated for the treatment of bacterial conjunctivitis.

Sprix (ketorolac tromethamine) Nasal Spray - formerly ROX-888

Company: Roxro Pharma, Inc.
Date of Approval: May 14, 2010
Treatment for: Pain
Sprix (ketorolac tromethamine) is an intranasal analgesic for the management of acute moderate to severe pain.

Natazia (dienogest and estradiol valerate) - formerly Qlaira

Company: Bayer HealthCare Pharmaceuticals Inc.
Date of Approval: May 6, 2010
Used for: Contraception
Natazia (dienogest and estradiol valerate) is a combination oral contraceptive indicated for use by women to prevent pregnancy.

Vimovo (naproxen and esomeprazole magnesium) - formerly PN 400

Company: Pozen Inc. and AstraZeneca
Date of Approval: April 30, 2010
Treatment for: Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis, NSAID-Induced Ulcer Prophylaxis
Vimovo is a combination of the pain reliever naproxen (NSAID) and esomeprazole magnesium (proton pump inhibitor) indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Provenge (sipuleucel-T) Suspension for Intravenous Infusion - formerly APC8015

Company: Dendreon Corporation
Date of Approval: April 29, 2010
Treatment for: Prostate Cancer
Provenge (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

Zortress (everolimus) Tablets - formerly Certican

Company: Novartis Pharma AG
Date of Approval: April 22, 2010
Used for: Organ Transplant -- Rejection Prophylaxis
Zortress (everolimus) is an oral inhibitor of the mTOR pathway indicated for the prevention of rejection of kidney transplants in adult patients at low-to-moderate immunologic risk.

NEW LAUNCHES

Ajinomoto launches scalable complex peptide synthesis

www.outsourcing-pharma.com
Ajinomoto AminoScience has launched AjiPhase, a peptide synthesis service which makes it practical and efficient to produce and scale up products that were previously considered too complex.

Expanding the range of peptides that can feasibly be produced and scaled up allows researchers to investigate new, more complex peptides, potentially enabling pharma to expand pipelines.

Furthermore, AjiPhase can be easily scaled up, removing the need to transition between solid phase peptide synthesis (SPPS) and liquid phase peptide synthesis (LPPS).

The shortcomings of SPPS and LPPS necessitate this transition and eliminating it can save development time and make revalidation of the impurity profile unnecessary.

Microfluidics launches continuous nanocrystallisation tech

www.in-pharmatechnologist.com
Microfluidics chose Interphex 2010 in New York, US to unveil a new processing technology that it claims can help manufacturers save time and money by switching from batch to continuous particle production.

The Microfluidics Reaction Technology (MRT) system combines active pharmaceutical ingredient (API) nanoparticle production with multiphase chemical reactions and nanoencapsulation in a single production unit.

This approach has a number of cost and timing advantages over traditional pharmaceutical nanoparticle production methods.

REGULATORY UPDATE

Rosuvastatin: new indication approved

The Food and Drug Administration (FDA) has approved the cholesterol-lowering medication rosuvastatin for some patients who are at increased risk of heart disease but have not been diagnosed. The new indication is for reducing the likelihood of a heart attack or stroke or the need for a procedure to treat blocked or narrowed arteries in patients who have never been told they have heart disease but are nevertheless at increased risk of a cardiac event.

Specifically, this includes men 50 years of age and older and women 60 years of age and older who have an elevated amount of a substance known as high sensitivity C-reactive protein in their blood and at least

one additional traditional cardiovascular risk factor such as smoking, high blood pressure, a family history of premature heart disease, or low amounts of high-density lipoprotein or HDL cholesterol.

US FDA widens mercury-skin lightening cream investigation

www.drugscontrol.org

The US FDA is broadening its investigation of mercury in skin-lightening creams after more than a dozen people using products in California and Virginia were found to have elevated levels of the toxic metal.

State and federal health officials linked the people's mercury levels to homemade skin lightening creams imported from Mexico.

In its investigation, the Tribune sent 50 creams to a certified lab for testing. Six of the creams were found to contain amounts of mercury banned by federal law. Of those, five had more than 6,000 parts per million of mercury - enough to potentially cause kidney damage over time.

The report spurred an international reaction as well

RESEARCH

Blood-Thinning Copycat Enters Malaria Fight

www.sciencedaily.com

New treatments for malaria are possible after scientists found that molecules similar to the blood-thinning drug heparin can stop malaria from infecting red blood cells.

The malaria parasite needs a protein called MSP1 if it is to infect red blood cells as MSP1 is involved in the initial attachment of the parasite to the cells.

We have shown that heparin-like carbohydrates bind to MSP1 which stops the parasite from properly attaching to the red blood cell and, therefore, from invading.

Although humans produce heparin-like molecules naturally, they do not occur at high enough levels in the blood to have anti-malarial activity. Heparin itself wouldn't be suitable as an anti-malarial as it prevents blood clotting. However, we have identified related compounds that are more potent against malaria than heparin but do not prevent blood clotting- these could form the basis of new antimalarial drugs.

Mannitol Boosts Effectiveness of Potential Cord Blood Treatment for Cerebral Palsy in Lab Animals, Study Finds

www.sciencedaily.com

The sugar-alcohol compound mannitol improved the therapeutic effectiveness of human umbilical cord blood cells injected into neonatal rat models of cerebral palsy, reports a new international study. The mannitol opened the blood-brain barrier by temporarily shrinking the tight endothelial cells that make up the barrier.

Intravenously-delivered human umbilical

cord blood (HUCB) may offer therapeutic benefits to those suffering from cerebral palsy if the blood cells can get past the blood-brain barrier to the site of injury. Also, the therapeutic effects were achieved without immunosuppression, which is often accompanied by harmful side effects.

Our present findings extend the usefulness of blood-brain barrier permeabilization in facilitating cell therapy for treating neonatal brain injury and potentially cerebral palsy.

Levitra, Herceptin combo used to target brain metastases

www.in-pharmatechnologist.com

Administration of Levitra (ildenafil) can increase Herceptin (trastuzumab) delivery to brain metastases, but not surrounding healthy tissue, increasing survival in mice, according to research.

The efficiency of Herceptin in treating tumours affecting the brain or central nervous system is believed to have been limited by the blood-brain tumour barrier (BTB). Now researchers believe that the class of drugs used to treat erectile dysfunction could help overcome the BTB. In a paper published online last month in PLoS One researchers detail an investigation into the impact Levitra, an erectile dysfunction drug, has on Herceptin delivery to brain metastases of lung and breast cancers.

Combining oral administration of Levitra and intravenous delivery of Herceptin increased survival time by 20 to 30 per cent in two of the three tumour types investigated compared to Herceptin alone. Furthermore, treatment with Levitra and Herceptin increased tumour apoptosis.

Long-Term Use of Parkinson's Drug May Impact Vision

www.sciencedaily.com

Parkinson's disease, the second most common neurodegenerative disease after Alzheimer's, is often treated with amantadine. The drug helps alleviate patients' motor problems and may be taken for years. Doctors have long known that amantadine treatment causes abnormal changes in the cornea in some Parkinson's patients. Usually corneal reactions occur soon after starting the drug and disappear a few weeks after it is withdrawn. But sometimes corneal disorders appear only after years of treatment, and the corneas of these patients often do not recover when amantadine is stopped.

Ophthalmologists and neurologists should consider evaluating a patient's corneal endothelium at the beginning of treatment with amantadine and reassess at regular intervals if the drug is used long term and additional monitoring would be needed for patients with other conditions that reduce ECD-such as recent cataract surgery or ongoing glaucoma, uveitis or Fuch's dystrophy-because corneal edema could develop during treatment.

MERGERS

GBI, Hyprocell collaborate to offer cell line development

www.outsourcing-pharma.com

CMO Goodwin Biotechnology Inc (GBI) is collaborating with Hyprocell to help clients that need manufacturing services but have a sub-optimal cell line producing low concentrations.

Joining with Hyprocell is intended to help GBI become a "one stop shop" capable of supporting clients' cDNA synthesis, transfection and clone selection needs, as well as process development and manufacturing.

DSM buys Upfront's Rhobust chromatography tech

www.outsourcing-pharma.com

DSM Biologics says combining its XD platform with newly-acquired Rhobust chromatography platform will create high yield, low cost bio-manufacturing option.

The US-based DSM unit has had its eye on the platform since September 2007 when it provided former owner, Danish purification technology specialist Upfront Chromatography, with funding to further its development.

Rhobust is an expanded-bed absorption (EBA) technology in which cross-linked tungsten carbide and agarose beads create a purification surface designed to improve recovery yields during bio-processing.

Colorcon buys NP Pharma

www.in-pharmatechnologist.com

Colorcon has acquired excipient business NP Pharm, adding sugar spheres to its portfolio and production capacity that will become an integral part of its manufacturing network.

NP Pharm, a division of Ethypharm, produces Suglets sugar spheres, for use in capsule and tablet formulation, which Colorcon believes will complement its SureSpheres product line. Both products are sugar spheres with applications in multiparticulate formulations.

Following the acquisition Colorcon will have access to NP Pharm's sugar sphere production site in Bazainville, France.

EyeGate, GSK collaborate on ocular delivery of drugs

www.in-pharmatechnologist.com

EyeGate Pharma is collaborating with GlaxoSmithKline (GSK) to evaluate the delivery of several of the big pharma's therapies using an ocular delivery system.

The aging population and rising prevalence of ophthalmic disease have created demand for improved ocular delivery methods. GSK will now assess the feasibility of using the EyeGate II delivery system to administer some of its therapeutics to the anterior and posterior of the eye.