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VEPACHEDU EDUCATIONAL FOUNDATION

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IP and Industry News

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First Gene Drug

The Food and Drug Administration has approved the first drug to treat melanoma by targeting a particular genetic mutation found in about half of skin cancer patients. The pill called Zelboraf is made by Roche. The FDA said it also approved a test to screen patients for the mutation. (www.fda.gov) About 68,000 people in the U.S. were diagnosed last year and 8,700 died, according to the American Cancer Society.

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Designer Drug

Researchers from Birmingham University claimed that a designer drug, also known as MDMA, could be used to treat leukaemia, lymphoma and myeloma after making it 100 times more effective at suppressing growth. Ecstasy was already known to be effective against more than half of white blood cell cancers, but previously the large dose required to treat a tumour would also have killed the patient. In a study published in the Investigational New Drugs journal, the scientists said the new drug could be used by doctors to treat cancer if it can be produced in a safe form. <http://www.telegraph.co.uk/science/science-news/8709920/Ecstasy-could-be-used-in-cancer-treatment.html>

Outsourcing

In a supercharged business and regulatory climate, life sciences companies large and small are turning to outsourcing vendors to manage tactical tasks and help them adopt best practices. In a constrained business environment, companies are finding that good partnerships bring added efficiencies, the potential for greater market share and the skills and capabilities that enable products to be brought to market more rapidly and maintained well in diverse markets. <http://www.drugdiscoverynews.com/index.php?newsarticle=5185>

Greed Got Us into this Mess

Greed seems to have no bounds in some quarters and it wreaks havoc on the industries where it abounds. A little more discipline and self-restraint can restore capitalism's good name. Both government and industry need to step up, wise up and do what is known to work. <http://www.drugdiscoverynews.com/index.php?newsarticle=5186>

China's Plan for Biotech

China is motivating scientists from the U.S. and within its own borders to start biotechs, and is planning to pump hundreds of billions into its biotech sector. The Chinese government reportedly has a 5-year plan to pour more than \$300 billion into the country's life sciences sector to create more than a million biotech jobs. Generous tax policies and government investments in start-ups are propelling new biotech activity in China. http://www.chinadaily.com.cn/bizchina/2011-08/19/content_13153498.htm

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Chinese officials have mapped out ambitious plans to generate a million new biotech jobs by the end of 2015. And they're backing those ambitious plans with \$308 billion of hard cash for science and technology. China to spend \$308B, gain 1M new jobs in 5-year biotech plan - FierceBiotech <http://www.fiercebiotech.com/story/china-spend-308b-gain-1m-new-jobs-5-year-biotech-plan/2011-06-28#ixzz1VWVBoU1>

With some of Big Pharma's top products losing exclusivity or facing fresh competition in the West, the new R&D game in the global drug industry is being played in Asia. Some of the biggest players have sunk a billion dollars into R&D facilities in the East--most notably China--as they begin to develop a new generation of therapies tailored for a market expected to grow at a rapid clip for years to come. And some, like Bayer AG, are cutting jobs in the U.S. and Europe as they shift focus and development strategies, notes a lengthy article in the *Wall Street Journal*. East beats West as Big Pharma shifts R&D efforts - FierceBiotech <http://www.fiercebiotech.com/story/east-beats-west-big-pharma-shifts-rd-efforts/2010-12-15#ixzz1VWwSM8E>

Do Patents Disclose Useful Information?

In an article entitled “Do Patents Disclose Useful Information?”, Lisa Larrimore Quелlette concludes that the technical value of patent disclosures is greater than many legal scholars appreciated, but also that many patents probably fail to meet the existing disclosure requirements. This seems particularly true for patents based on the legal fiction of constructive reduction to practice—many experiments do not work the way one might expect, so it would require undue experimentation for a PHOSITA to create many speculative inventions. And disclosure problems will likely get worse with the likely switch to a first-to-file system, in which racing to the PTO (perhaps with an incomplete disclosure) becomes more important.

She suggests that disclosure requirements should be enforced, and even strengthened, and argues that the best way to accomplish this is to get scientists even more engaged with the patent literature. For example, the PTO could send patents to scientists for peer review or patentees could be obligated to respond to enablement questions from other scientists. The patent literature should also become more accessible to

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scientists (including by removing legal barriers to its use). Bringing patents more in line with scientific norms will benefit both patent law and the scientific community. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1762793

Big Pharma Lay Offs, Brain Drain

To cope with projected revenue declines and margin erosion as some blockbuster drugs went off their patents, companies consolidated. Among them the 2009 Pfizer Inc. acquisition of Wyeth. Those consolidations, in turn, led to thousands of people being out of work. http://articles.philly.com/2011-08-21/business/29911965_1_pharmaceutical-industry-drug-pricing-wegmans

Golden Era of Research

Describing a "golden era" of research, Harpal Kumar, the chief executive of [Cancer Research UK](http://www.guardian.co.uk/science/2011/aug/22/cancer-research-golden-era), said there has been "an explosion in our understanding of what cancer is, why it happens, why it doesn't happen in some people and why it moves around the body." <http://www.guardian.co.uk/science/2011/aug/22/cancer-research-golden-era>

There are encouraging signs that the pharmaceutical industry's pipeline of new products is not as stalled as some say. Already in 2011, the Food and Drug Administration (FDA) has approved 21 new, groundbreaking medicines—the same number as in all of 2010—including treatments for Hepatitis C, late-stage prostate cancer and lupus. <http://online.wsj.com/article/SB10001424053111904888304576474072017155038.html>

Non-Obviousness of Pharmaceutical Formulations

The United States District Court for the Southern District of New York heard a dispute between Apotex, Inc. and Apotex Corp. ("Apotex"), the appellants, and Unigene Laboratories, Inc. and Upsher-Smith Laboratories, Inc. (collectively, "Unigene"), the appellees, over claim 19 of U.S. Patent No. RE40,812E ("812E patent"). On cross-motions for summary judgment, the district court granted Unigene's motion

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that the patent would not have been obvious at the time of invention. Unigene Labs., Inc., v. Apotex, Inc. (“Summary Judgment Opinion”), No. 06-CV- 5571, Dkt. No. 175, slip op. at 28-29 (S.D.N.Y. Aug. 31, 2009).

On appeal, the Federal Circuit the district court’s grant of summary judgment of nonobviousness in favor of Unigene, affirms the district court’s denial of summary judgment of obviousness.

Unigene owns the ’812E patent through assignment from inventor Dr. William Stern (“Stern”). The ’812E patent is a reissue of U.S. Patent No. 6,440,392 (“’392 patent”). The reissue occurred on June 30, 2009, while this case was before the district court.

Covered by the ’812E patent, Fortical® is an Food and Drug Administration (“FDA”) approved pharmaceutical nasal spray with the active ingredient salmon calcitonin (“salmon calcitonin” or “calcitonin”). Unigene filed for FDA approval under 21 U.S.C. § 355(b)(2) and now holds the New Drug Application (“NDA”) for Fortical®. Unigene’s NDA claims Miacalcin® as its reference drug, meaning that for FDA approval, Unigene had to prove that Fortical® was a bioequivalent of Miacalcin®. Upsher-Smith is the exclusive patent licensee, with rights to market and sell Fortical® in the United States. Fortical® treats, among other things, postmenopausal osteoporosis.

Fortical® is a bioequivalent of Novartis International AG’s Miacalcin® calcitonin nasal spray. Miacalcin® has been marketed since 1995, before the ’812E patent’s February 4, 2000 priority date. Unigene developed Forti- cal® as an alternative to Miacalcin®.

Both Miacalcin® and Fortical® use salmon calcitonin at a concentration of 2,200 I.U./mL as their active ingredient. Salmon calcitonin is a natural polypeptide hormone. Calcitonins help regulate calcium ions in the blood and therefore address calcium-related conditions like osteoporosis. To be effective, polypeptides, like salmon calcitonin, must reach the bloodstream. Delivery to the bloodstream, however, is not easy because calcitonins are readily degraded by bodily fluids, are relatively unstable in pharmaceutical compositions, and are poorly absorbed through tissues. Miacalcin® and Fortical® are both nasal sprays.

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Fortical® and Miacalcin® have different formulations. For instance, Miacalcin® also contains 8.5 mg of sodium chloride, which acts as a tonicity agent; nitrogen, which acts as a sparging agent; hydrochloric acid, which acts as a pH adjuster; and purified water, which acts as a carrier. Of particular importance to this appeal, Miacalcin® contains 0.10 mg of benzalkonium chloride (“BZK”) which functions as a preservative, absorption enhancer, and surfactant. In contrast, Fortical® contains 20 mM of citric acid, which functions as an absorption enhancer and stabilizer/buffer; polyoxyethylene(2) sorbitan monooleate (“polysorbate 80”), which acts as a surfactant; and phenylethyl alcohol and benzyl alcohol, which serve as preservatives.

Based on the above facts, the Federal Circuit reasoned, “[t]o a person of ordinary skill in the art, citric acid, even at about 20 mM concentrations, would not be an obvious substitute for BZK’s functions as an absorption enhancer and as a surfactant because citric acid has a vague role in even the closest prior art. See *Eli Lilly*, 471 F.3d at 1380.... Thus, the “about 20.0 mM citric acid” limitation alone supports the district court’s grant of summary judgment of nonobviousness. When used as an absorption enhancer in the ’116 patent, citric acid was one of over fifty options. See *KSR*, 550 U.S. at 421. Further, when the prior art used citric acid at about 20 mM, as in the ’315 patent, it was used only as a buffer. There is no genuine dispute of material fact that a person of ordinary skill attempting to make a liquid composition to deliver salmon calcitonin into a human body through nasal administration, would not have considered using about 20 mM citric acid with the narrowly claimed amounts of benzyl alcohol, phenylethyl alcohol, and polysorbate 80, because the formulation would not be expected to perform properly to meet the specificity of a pharmaceutical use. Thus, even accepting that there was a design need and market pressure to develop a pharmaceutical formulation that is bioequivalent to Miacalcin®, there is no evidence in the record that claim 19 would be an obvious solution to those motivations.” [Unigene Labs., Inc. v. Apotex, Inc. \(Fed. Cir. 2011\)](#), Chief Judge Rader and Circuit Judges Moore and O’Malley

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India and EU Generics Deal

Three years after a dispute erupted over the seizure by EU authorities of Indian-made generics as they were being shipped through Europe, India and the European Commission have struck an interim deal that restricts the 27 member EU states from seizing meds unless there is evidence that drugs will be diverted in the European Union, according to a [statement](#) from the Prime Minister's office in India.

The seizures were made after EU authorities in various countries, starting with The Netherlands, maintained the generics violated intellectual property rights and were, therefore, counterfeit. The actions infuriated Indian generic drugmakers, because exporters would be forced to find alternative routes to send shipments, which would increase costs and hurt competitiveness. <http://www.pharmalot.com/2011/08/india-and-eu-reach-a-deal-on-generic-seizures/>

Turmeric for Pain Relief

Curcumin, which gives the Indian spice turmeric its bright yellow color, could be helpful in treating painful inflammatory conditions, such as tendinitis and arthritis, according to researchers at the University of Nottingham in the U.K. and Ludwig-Maxmillians University in Munich, Germany. Their studies show that curcumin can be used to suppress inflammation in tendon diseases. http://articles.timesofindia.indiatimes.com/2011-08-14/health/29871399_1_spice-turmeric-curcumin-arthritis

Lupron for Central Precocious Puberty

Central precocious puberty is a condition in which puberty starts too early in children. This occurs in one child of every 5,000 to 10,000 children and is more common in girls. During puberty, the brain produces a hormone called gonadotropin-releasing hormone (GnRH). Through a complex process, GnRH causes increases in other hormones like luteinizing hormone (LH) and follicle stimulation hormone (FSH). It is these hormones that cause the ovaries to produce estrogen and the testicles to produce testosterone. With central precocious puberty, girls under the age of 8 and boys under the age of 9 begin to develop signs of puberty. Doctors may diagnose children with CPP when signs of sexual maturity begin to develop in girls

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under the age of 8 or boys under the age of 9. Abbott announced that the U.S. Food and Drug Administration (FDA) has approved two new strengths for three-month administration of Lupron Depot-PED ® (leuprolide acetate for depot suspension) for the treatment of children with CPP. <http://www.biospace.com/News/abbott-laboratories-receives-fda-approval-for-two/230476>

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!

(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

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