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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Big Pharma

Last year, the U.S. Food and Drug Administration's drugs division approved just 21 novel medicines -- less than half the level seen in 1996 and 1997. The \$850-billion-a-year industry still doesn't have nearly enough new drugs to replace all those facing generic competition in the biggest wave of patent expirations in history.

Pfizer has taken the most dramatic steps to slash around a quarter of its R&D budget over the next two years as its labs focus only on the most lucrative areas, as a number of huge products, like Pfizer's \$11-billion-a-year cholesterol fighter Lipitor goes off patent soon in 2011. Sanofi and Bristol-Myers Squibb's blood thinner Plavix goes off patent in 2012. GSK has already cut back on research, with the number of staff working in R&D down 28 percent since 2006. It may go down more -- but further cuts will be constrained by the need to pay for a bunch of large late-stage clinical trials. Not all drugmakers agree with the approach of Pfizer's approach. Merck & Co opted to withdraw its long-term profit forecast rather than take a hatchet to its research budget. Over all, it is a lousy time to work in a drug lab. <http://www.reuters.com/article/2011/05/11/us-summit-rd-idUSTRE74A3JA20110511>

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Some industry executives see the possibility of an even more drastic pruning, whittling the top 25 players down to six or eight massive drug companies, supported by service firms and smaller innovative players. <http://www.reuters.com/article/2011/05/11/us-summit-bain-idUSTRE74A67520110511>

In 2008, a total of 78 percent of all subjects participating in trials to support drug applications submitted to the Food and Drug Administration (FDA) were enrolled at foreign sites. In Europe, the picture is similar, with 61 percent of patients in pivotal trials submitted to the European Medicines Agency (EMA) between 2005 and 2009 coming from third countries. Today, the clinical trials business has gone global as drugmakers seek cheaper venues for studies and cast their net further afield for big pools of "treatment-naive" patients who are not already taking other drugs that could make them unsuitable subjects for testing new ones. The drug industry is also paying a lot more attention to the promise of emerging markets. <http://www.reuters.com/article/2011/05/06/us-pharmaceuticals-trials-idUSTRE7450SV20110506?feedType=nl&feedName=ushealth1100>

The chairman of the Senate's antitrust panel urged the Federal Trade Commission to pay special attention to prescription drug shortages when weighing whether to approve pharmaceutical industry mergers. "Maintaining a competitive pharmaceutical market is the highest priority, and these reports of drug shortages are very troubling to me," Sen. Herb Kohl (D-Wis.) wrote to FTC Chairman Jonathan Leibowitz. "While I recognize that often shortages are likely to have causes not related to these competition issues, antitrust enforcers — particularly when reviewing drug company mergers — must be cognizant of these shortages when applying antitrust law to the drug industry." <http://thehill.com/blogs/healthwatch/medical-devices-and-prescription-drug-policy-162153-kohl-urges-trade-officials-to-be-wary-of-drug-industry-consolidation>

Crepe Jasmine and Conolidine

Tabermontana divaricata (crepe jasmine or butterfly gardenia) is native to tropical areas of Indian continent and is widely grown for its ornamental value in frost free areas around the world. Crepe

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jasmine is a beautifully shaped evergreen shrub which forms symmetrical 6 ft (2 m) high mounds of glossy foliage. The many branches tend to grow almost parallel to the ground giving the shrub an attractive horizontal aspect. Like many members of the Apocynaceae family, the stems of crepe jasmine exude a milky latex when broken. The large shiny leaves are deep green and are 6 or more inches (15 cm) in length and about 2 in (5 cm) in width. Crepe jasmine blooms in spring but flowers may appear sporadically all year. http://www.floridata.com/ref/t/tabe_div.cfm

Conolidine, an indole alkaloid and rare member of C5-nor stemmadenines family, was first isolated from the stem-bark extract of the Malayan *Tabernaemontana divaricata* in 2004. Scientists from the Florida campus of The Scripps Research Institute have for the first time accomplished a laboratory synthesis, published May 23, 2011, in an advanced online edition of the journal *Nature Chemistry*. Long part of traditional medicine in China, Thailand, and India, extract from the leaves has been used as an anti-inflammatory applied to wounds, while the root has been chewed to fight the pain of toothache. Other parts of the plant have been used to treat skin diseases and cancer. While still in the early stages of development, further characterizations of conolidine may suggest further development as a human therapeutic for the treatment of pain.

<http://www.sciencedaily.com/releases/2011/05/110523075316.htm>

Inequitable Conduct

Inequitable conduct, a judge-made doctrine, is an equitable defense to patent infringement barring enforcement of a patent. This doctrine evolved from Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct: *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). The unclean hands cases of *Keystone*, *Hazel-Atlas*, and *Precision* formed the basis for the doctrine of

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inequitable conduct. To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. This developed and evolved over time to become a “plague” and common litigation tactic. One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct, many of them on “the slenderest grounds.” Low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality.

The Court of Appeals for the Federal Circuit (CAFC) tightened the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public. In an *en banc* decision in *Therasense, Inc. v. Becton, Dickinson and Company* (Fed. Cir. 2011), the CAFC vacated the judgment of inequitable conduct and remanded. See <http://www.patentlyo.com/therasensefrompatentlyo.pdf> and <http://www.patentlyo.com/patent/>.

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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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