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The Andhra Journal of Industrial News

IP and Industry News

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Swiss-type Claims

Claims to methods of medical treatment are not allowable under European patent law (see Article 52(4) of the European Patent Convention (EPC)). Accordingly, claims to second medical uses of known substances have traditionally been drafted in a format called Swiss-type format "*use of substance X for the manufacture of a medicament for the treatment of disease Y.*"

Amendments to the EPC (EPC 2000) allowed second medical use claims without the wording of Swiss-type claims. These purpose-limited product claims have the format "*Substance X for use in the treatment*

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of disease Y." The EPC 2000 amendments entered into force on 13 December 2007. Since then both Swiss-type and purpose-limited product claims have been allowed by the European Patent Office (EPO).

The Enlarged Board of Appeal at the EPO held in its G2/08 decision of 19 February 2010 that in light of the EPC 2000 amendments, the Swiss-type claim format should no longer be used for second medical use claims. The Enlarged Board set three months from publication of its decision in the EPO Official Journal for compliance by future applications. Publication took place on 28 October 2010. Therefore, patent applications filed after 28 January 2011 the Swiss style format will no longer be acceptable in Europe.

It may be a good idea to include both Swiss-type and purpose-limited product claims in Patent Cooperation Treaty (PCT) applications as Swiss-type claims are still allowable in certain jurisdictions such as Australia, New Zealand and China.

Business Method Claims in Canada

The Federal Court of Canada, in *Amazon.com Inc. v. Canada (Commissioner of Patents)*, 2010 FC 1011, (October 14, 2010), concluded that a 'business method' can be patented in appropriate circumstances. By applying the technology neutral test for the patentability of processes to business methods the Court has endorsed a broader scope of patent protection for computer related inventions in Canada. The Court confirmed that the test enunciated in *Progressive Games* for the patentability of arts and processes applies to business methods. The decision provides the following guidance, contrary to certain (past) practices of the Canadian Patent Office:

- There is an "absolute lack of authority in Canada for a 'business method exclusion'" to what constitutes patentable subject matter;
- Inventions need not be either physical in nature or effect and tangibility is not an issue;
- There is no requirement that inventions be technological;

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- It is improper to parse out the novel and known elements of an invention for the purpose of determining patentability based on the novel elements alone.

Advantages and Disadvantages of Patents

The costs associated with patent infringement are prohibitive. It may be a good idea to consider keeping the technology "secret" to avoid the expensive patenting process which only leads to further expensive litigation. Read an article on such a dilemma at: http://www.mondaq.com/unitedstates/article.asp?articleid=118144&email_access=on or *The Business Suit* - Volume 13 Issue 8: <http://www.babc.com/to-be-patented-or-not-to-be-patentedthat-is-the-question-10-14-2010/>

The R&D Revolution-Phase II in Indo-China

According to John Carroll at FierceBiotech, if 2009 was the year of the mega-merger, 2010 was the year of continuing R&D reorganization, downsizing and evolution. As partnering became all the rage, the old reliance on in-house ops began to fade--slowly. In 2010, Pfizer promised to whack 100 of the research programs it had in its pipeline after merging with Wyeth, Sanofi's R&D budget had been cut by 7%, Abbott announced cuts, GSK looked to R&D for much of the \$1.4 billion it needed to cut, and AstraZeneca is trimming a billion dollars in costs out of its research operations by 2014. With R&D operations exploding in China and India, an international survey conducted by AstraZeneca found a strong belief that the two Asian countries are on their way to overtaking the U.S. and Japan as the most innovative countries on the planet. (http://www.fiercebiotech.com/story/2010-rd-revolution-phase-ii/2010-12-23?utm_medium=nl&utm_source=internal)

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No wonder, it would be a self-fulfilling prophecy as Big Pharma moves its R&D operations to China and India, by killing R&D in the US. By the end of November, drugmakers had cut more than [50,000 people from their payrolls](#). Big mergers claimed thousands of jobs as companies sought to wring costs from their combined operations. Sales forces were hit by delayed approvals and generic competition. And some companies--Bristol-Myers Squibb, for instance, [which is cutting 840](#)--simply tightened their belts across the board. AstraZeneca started the year with the announcement that it would [slash 8,000 jobs company-wide](#), including 4,450 in sales, marketing and administration. Roche announced it would cut 4,800 jobs and lose another to reshuffling, with a total of 6,300 positions affected, 2,650 of them in sales and marketing because of a drug-development delay. [Abbott Laboratories announced 3,000 cuts](#); Bayer said it would [cut back by 4,500](#) in established markets as it staffed up by 2,500 in other spots, particularly Asia. Sanofi-Aventis [reduced head count by 1,700](#), wielding the axe in early December. Takeda Pharmaceutical announced [1,400 sales cuts in the U.S.](#) because of generic competition for blockbuster diabetes drug Actos. And Novartis said it would cut 1,400 from its sales force. That Pfizer was shrinking payrolls as it brings Wyeth operations into the fold wasn't a surprise; the company detailed plans to shut down and consolidate manufacturing and R&D as part of its bid to cut 15 percent, or about 19,500 jobs from the combined company. At the same time, Merck was working to shutter eight plants and eight R&D sites as it continued with its plans to shave 16,500 from its workforce. At year's end, industry observers were predicting more job cuts to come. Who's next? (Read more: [Another year of cuts as layoffs hit 50,000 - FiercePharma](#) <http://www.fiercepharma.com/story/another-year-cuts-layoffs-hit-50000/2010-12-23#ixzz19BNqra9Y> <http://www.fiercepharma.com/special-reports/top-10-layoffs-2010>)

Pharma operations will show signs of suffering from this evaporation of experience, just as the telecom industry did in the 1990s following big force reductions. ([Pharma ops jobs enter long dark tunnel - FiercePharma Manufacturing](#) <http://www.fiercepharmamanufacturing.com/story/pharma-ops-jobs-enter-long-dark-tunnel/2010-12-22#ixzz19BRaBIIM>) Pharma's shift into emerging markets and away from established sales and marketing routines leads to permanent job cuts, says *The Economist*. That's in contrast to job cuts that normally accompany a recession, which are reversible when the economy

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improves. Jobs that are disappearing now will probably not reappear, but that may help save other jobs by shoring up pharma company profits. (http://viewswire.eiu.com/index.asp?layout=ib3PrintArticle&article_id=1827637367&printer=printer&rf=0)

Accident at Dr. Reddy's Laboratories

The Indian pharmaceutical firm Dr Reddy's Laboratories Ltd announced death of two people in accident in plant caused by gas leakage. An employee and a contract worker died in the incident that occurred at the company's plant in the southern state of Andhra Pradesh. The police are investigating the incident that occurred around midnight on December 22. The plant is approved by the U.S. Food and Drug Administration and makes bulk drugs, a company official said.

Setbacks

Astra and partner Abbott Laboratories have abandoned plans to develop their experimental heart drug Certriad, after US regulators rejected the drug in March and asked for more information.

It's third time unlucky for [AstraZeneca](#) as its announces another setback in its drug pipeline. Astra's blood-thinning drug Brilinta - expected to be a multi-billion dollar blockbuster - had failed to win approval from US regulators and Astra had discontinued development of its experimental drug Motavizumab for preventing lung disease in infants.

With Big Pharma pipelines undergoing a massive overhaul in the wake of mega-mergers and a wholesale review of pipeline priorities, analysts at Deloitte Recap say that changed pipeline priorities have become the main reason for major deal disruptions since they began gathering data in 1977. And the program switch-ups played a key role in this year's top 10 deal terminations, featured in the chart. ([Top 10 deal](#)

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terminations in 2010 - FierceBiotech http://www.fiercebiotech.com/special-reports/top-10-deal-terminations-2010?utm_medium=nl&utm_source=internal#ixzz19BWtncdS)

Counterfeits

Drug counterfeiting has become a [\\$200-billion business annually](#), according to the World Customs Organization. By some calculations, the counterfeiting trade has become more lucrative than the narcotics business. It's a global problem. The World Health Organization estimates that counterfeit drugs make up ten percent of the drug market worldwide. That breaks down to 30 to 40 percent (sometimes higher) in developing countries versus perhaps one percent in developed countries. But counterfeits are on the rise in developed countries, thanks largely to the prevalence of online pharmacies. The FDA periodically buys drugs online and routinely finds that more than half are fakes. ([Top Counterfeit Drugs Report - FiercePharma Manufacturing](#) <http://www.fiercepharmamanufacturing.com/special-reports/top-counterfeit-drugs#ixzz19BTWSmkn>)

Patentability of Diagnostic Claims

In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008-1403 (Fed. Cir. 2010), the Federal Circuit held that Prometheus's asserted method claims satisfied the preemption test as well as the transformation prong of the machine- or-transformation test. This affirmed that personalized medicine and medical diagnostic claims are not *per se* unpatentable for claiming natural phenomena. The patent-eligibility of such claims has been in question since the Supreme Court's dismissal of the grant of certiorari in *Laboratory Corp. of American Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006). Supreme Court Justice Breyer dissented from the dismissal and wrote a non-binding opinion that "detecting" and "correlating" claims were not patent-eligible. More recently, the Supreme Court decision to vacate and remand the Federal Circuit's 2009 *Prometheus* decision in view of its decision in *Bilski v. Kappos*, 130 S.Ct. 3218 (2010), raised questions about the patent-eligibility of such methods. The Federal Circuit will have another opportunity to address the patent eligibility of diagnostic and personalized

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medicine methods in *ACLU v. Myriad* (BRACA I) case. <http://www.ca9c.uscourts.gov/images/stories/opinions-orders/08-1403.pdf>

Regional USPTO at Detroit

On December 16, 2010, U.S. Commerce Secretary Gary Locke announced that Detroit will be the site of the first satellite or "regional" office for the USPTO. Secretary Locke and Director Kappos cited the backlog of pending applications — currently more than 700,000 — and the difficulty in recruiting qualified patent examiners to the Washington, D.C. area. According to the USPTO Patent Dashboard, on average the USPTO does not grant a patent until 34.9 months after the filing date. Selection criteria considered for Detroit included the concentration of scientists and engineers, access to universities, volume of patent activity, and the number of patent attorneys and agents in the area. Future sites are being considered. The Detroit regional office is expected to open in 2011 and will be staffed with more than 100 new employees, most of whom are expected to be hired out of the Detroit area. According to Director Kappos, many of the new examiners will specialize in fields compatible with new innovations taking shape in the Detroit region. http://www.uspto.gov/news/pr/2010/10_65.jsp

Cloud Computing

Cloud computing is Internet-based computing; it involves the use of remote computing resources that are usually shared and/or distributed rather than dedicated and centrally located. Cloud computing is generally a subscription-based service that satisfies both computing and storage needs with an infrastructure based in the Internet. Cloud computing, thus, is physically limitless, and can then be accessed by users "on demand" from virtually anywhere with an Internet connection with minimal administrative effort. This service is managed by a third-party provider rather than an internal IT department. For example, Gmail, Google's free email service, stores email "in the cloud" which means

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that any user's email "mailbox" may actually be stored in one of several different servers located all over the world and can easily be accessed from anywhere on the Internet. Some of the benefits of cloud computing are that it potentially reduces costs and increases efficiency by freeing a company's IT department from the need to own and service its own hardware and software. Thus, many businesses are seeking to take advantage of the still-evolving technological development. http://www.mondaq.com/unitedstates/article.asp?articleid=116916&email_access=on

http://www.mondaq.com/unitedstates/article.asp?articleid=118008&email_access=on

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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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