



BioTechCircle News®

March, 2004

In this issue:

- Links to 57 Web articles of interest to the biotech community: technology, markets and business. NOTE: if links do not work automatically, simply highlight the entire link address and paste into your browser.
 - Biotech Patent Watch for discovering licensing or work opportunities (in 2 separate e-mails): 66 gene-related patents issued and 181 patent applications posted in February, 2004. You may copy and paste the data into your own spreadsheet for further analysis.
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Links to 57 Web articles in 12 categories:

- 1) Agri-biotech (4 articles)
 - 2) Biobusiness Management (6 articles)
 - 3) Clinical Trials (1 article)
 - 4) Contract Services (4 articles)
 - 5) Drug Delivery (1 article)
 - 6) Industry (6 articles)
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 - 12) Therapeutic Category (22 articles)
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1)AGRIBIOTECH (4 articles)

ANIMAL

What Could Happen If Genetically Modified Fish Get Loose

Cheryl Simon Silver, Genome News Network (February 20, 2004)

Reports on a study confirming that genetically modified fish, if released to the wild, may create havoc in natural stocks, hastening their extinction. So far, about 20 species have been genetically modified, mostly for size.

<http://www.genomenewsnetwork.com/articles/2004/02/20/fish.php>

CROPS

Britain Gives Go-ahead for First GM Crop

Andy Coghlan, New Scientist (March 4, 2004)

Reports on Britain's approval of Bayer's Chardon LL maize, engineered to be resistant to the weedkiller glufosinate ammonium, as its first genetically modified crop for commercial growing. Two others have been rejected.

<http://www.newscientist.com/news/news.jsp?id=ns99994754>

GM Under Fire Again

Mark Peplow, Nature (March 5, 2004)

Reports on the predicted negative impact on the environmental benefits of genetically modified (GM) maize with an impending European ban on certain herbicides, called triazines.

<http://www.nature.com/nsu/040301/040301-12.html>

LAB-ON-A-CHIP/ DNA CHIPS/ MICROARRAY

DNA Chip Will Catch Beefed up Chicken

Andy Coghlan, New Scientist (March 4, 2004)

A single test, based on a DNA chip, can now reveal the presence of meat from any of 32 different species in food samples. The test is being evaluated by food regulatory authorities in Europe, and could be used by supermarkets to check on their suppliers.

<http://www.newscientist.com/news/news.jsp?id=ns99994735>

2)BIO-BUSINESS MANAGEMENT (6 articles)

BIOMANUFACTURING

Training Day for International Biopharma Manufacturers

Eric S. Langer, Contract Pharma (March 1, 2004)

Langer says the lack of trained and experienced technical and production staff during the next five years is a key factor that the industry predicts will create production bottlenecks. Table on factors creating capacity

constraints by 2008.

<http://www.contractpharma.com/March041.htm>

Disposable Components Enable a New Approach to Biopharmaceutical Manufacturing

Geoffrey Hodge, BioPharm International (March 1, 2004)

Examines how the emerging field of single-use, disposable components can help to improve manufacturing operations with regard to speed, cost, and quality.

<http://www.biopharm-mag.com/biopharm/article/articleDetail.jsp?id=87975>

DATA INTEGRATION

Data System Trumps Paper, Scissors, Glue

Salvatore Salamone Bio-IT World (February 18, 2004)

Describes how a pharmaceutical developer reduced the time spent cutting and pasting computer-generated data into notebooks through implementation of an electronic data collection system. Results include faster FDA filings and patent application preparation.

http://www.bio-itworld.com/news/021804_report4454.html

GENERAL/ ADMINISTRATIVE

The 11-Day Week

Ronald S. Waife, Applied Clinical Trials (March 1, 2004)

What is the connection between seven solar days and the habit of holding weekly meetings? Waife notes that the price of the Digital Age is round-the-clock phone calls and air travel demands and advises a serious review of meeting and report scheduling.

<http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=86721>

GOVERNMENT/APPROVALS

Feds to Biotech: No More Fibbing!

Business Week (February 17, 2004)

Explains a little-noted change in drug-approval procedures as a step toward avoiding more ImClone-style stock scandals.

http://www.businessweek.com/technology/content/feb2004/tc20040220_5051_tc122.htm

21 CFR Part 11 - Requirements and New Scope

Ludwig Huber and Wolfgang Winter, BioPharm International (February 15, 2004)

Describes the rule's interpretation and enforcement as of January 2004 applying to FDA-regulated industry segments that must follow Good

Laboratory Practice (GLP), Good Clinical Practice (GCP), and current Good Manufacturing Practice (cGMP) requirements.
<http://www.biopharm-mag.com/biopharm/article/articleDetail.jsp?id=89956>

3) CLINICAL TRIALS (1 article)

MISCELLANEOUS

The Marketing of Trials

Toby Jane Hindin, Applied Clinical Trials (March 1, 2004)

Hindin observes that the many avenues of information continue to be ineffective in recruiting the required number of subjects and that public relations tactics may lead to public perception of the clinical trial as just another product campaign.

<http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=86129>

4) CONTRACT SERVICES (4 articles)

INDUSTRY, GENERAL

Beyond the CRO

Steven Heffner, Contract Pharma (March 1, 2004)

Illustrates where contract development money was spent in 2003 and predicts that other players, such as academic medical centers and teaching hospitals, laboratory (analytical) service companies, site management organizations, and niche players.

<http://www.contractpharma.com/March044.htm>

MISCELLANEOUS

CROs and EDC Vendors

Edward F. Ikeguchi, Contract Pharma (March 1, 2004)

The industry of contract research has contributed significantly to the effectiveness of Pharma and Biopharma as an invaluable resource.

Focuses on Electronic Data Capture (EDC) relationships between vendors and sponsors.

<http://www.contractpharma.com/March042.htm>

Taking on Six Sigma Programs

Joong Hyun, Contract Pharma (March 1, 2004)

Provides guidelines for selecting external assistance for proper six sigma training and development of internal resources and for delivering

bottom-line results.

<http://www.contractpharma.com/March043.htm>

Stakes Getting Higher for Contractors

Jim Miller, Pharmaceutical Technology (March 1, 2004)

Predicts that contractors can expect to see higher insurance premiums for errors and omissions coverage and a lowering of coverage limits, as drug companies are taking a harder stance on "consequential damages."

<http://www.pharmtech.com/pharmtech/data/articlestandard/pharmtech/102004/87724/article.pdf>

5) DRUG DELIVERY (1 article)

MISCELLANEOUS

Drug Delivery

David Filmore, Modern Drug Discovery (March 1, 2004)

Filmore reports that drug delivery methods often help to bridge the gap between preclinical promise and feasible drugs. Explains how electroporation is used for in vitro gene transfection of cell lines.

<http://pubs.acs.org/subscribe/journals/mdd/v07/i03/pdf/304patents.pdf>

6) INDUSTRY (6 articles)

GENERAL

The New Product Parade

Jennifer Van Brunt, Signals (February 6, 2004)

Presents detailed information and tables on the 25 new biotech and biotech-derived medicines approved by the FDA in 2003.

<http://www.signalsmag.com/signalsmag.nsf/0/E1E096FAA054A59A88256E32006BEBFF>

A Risky Bet on Antibiotics?

Amy Tsao, Business Week (March 15, 2004)

Eager for reliable revenue streams, biotechs are increasingly looking to an area that the pharmaceutical industry has long overlooked -- antibacterial drugs, better known as antibiotics.

http://www.businessweek.com/technology/content/mar2004/tc20040315_8816_tc122.htm

Operations Excellence: BioPharma Consortium Discusses Key Industry Trends

Amir London, BioPharm International (March 1, 2004)

Reviews challenges posed by biogenerics, the risks and rewards of standardizing on a single platform the development and making of products, cycle-time reduction and other topics.

<http://www.biopharm-mag.com/biopharm/article/articleDetail.jsp?id=87942>

GEOGRAPHIC FOCUS

California Dream

Randall C. Willis, Modern Drug Discovery (March 1, 2004)

Reports that "San DNago" has caught the surging biotech wave through the scientific strength of its local universities and research institutes as well as programs introduced by community colleges. Charts compare San Diego with Boston and San Francisco.

<http://pubs.acs.org/subscribe/journals/mdd/v07/i03/pdf/304willis.pdf>

Japan: Discover Asia's Largest and the World's Second Largest Biotechnology Market

Osamu Chisaki, BioPharm International (March 1, 2004)

Discusses high profitability of Japan's big pharmaceutical companies and how those companies are coping with the challenges of conducting clinical trials in Japan, high R&D expenditure requirements and others.

<http://www.biopharm-mag.com/biopharm/article/articleDetail.jsp?id=88003>

New Outsourcing Law Readies Japanese Companies for Global Pharmaceutical Markets

Janet Lowenbach, Outsourcing Journal (March 1, 2004)

Discusses the revised Pharmaceutical Affairs Law, scheduled for implementation in April 2005. Companies will be able to manage outsourcing through a new marketing authorization system similar to those of the United States and the European Union (EU).

<http://www.outsourcing-journal.com/mar2004-japan.html?email005116>

7) MEDICAL DEVICES (1 article)

MISC. MEDICAL DEVICES

New Wrinkles in Drug Delivery

Celia M. Henry, Chemical & Engineering News (March 1, 2004)

Drug delivery companies are starting to position their technologies earlier in the drug development timeline, as they can no longer rely on their platform technologies but need tangible products to impart value.

<http://pubs.acs.org/cen/coverstory/8209/8209drugdelivery.html>

8) NOVEL APPLICATIONS (1 article)

MISCELLANEOUS

Genome Music: “Searching for the Individual”

Cheryl Simon Silver. Genome News Network (February 20, 2004)

Reports on the musical expression Spanish scientists achieved when they translated genetic code into musical notation.

http://www.genomenewsnetwork.com/articles/2004/02/20/genoma_music.php

9) PHARMACEUTICALS (1 article)

BIOINFORMATICS

A Preventable Informatics Crime

Michael Athanas, Bio-IT World (February 18, 2004)

Discusses the attractiveness of cluster computing (between 4 and 50 times cheaper than symmetric multiprocessors) and the challenging problem of applications, pipelines, and workflows taking advantage of the technology.

<http://www.bio-itworld.com/archive/021804/box.html>

10) PLATFORM TECHNOLOGIES (8 articles)

ANTIBODIES

Armed Antibodies

Jennifer Van Brunt, Signals (March 5, 2004)

Reviews the road to monoclonal antibody-based therapies approved by the FDA for treatment of immune disorders, infectious diseases and cancer.

Tables of approved therapies and armed antibodies under development.

<http://www.signalsmag.com/signalsmag.nsf/0/62E6FFD4E88AC56188256E4E00684CB6>

BIOINFORMATICS

Betting on Bioinformatics

Michael J. Felton, Modern Drug Discovery (March 1, 2004)

Explains IBM's dominance in life sciences IT through its strategic decisions and presents observations by its partners, such as NuGenesis.

<http://pubs.acs.org/subscribe/journals/mdd/v07/i03/pdf/304felton.pdf>

DRUG DISCOVERY

Challenges of Small-RNA Purification

Sapma Chacko and Emmanuel Labourier, *Modern Drug Discovery* (March 1, 2004)

Obtaining high-quality, intact RNA is the first and often the most critical step in performing many fundamental molecular biology experiments. Describes several methods.

<http://pubs.acs.org/subscribe/journals/mdd/v07/i03/pdf/304toolbox.pdf>

Enzymes Stitch Together Non-natural DNA

Philip Ball, *Nature* (February 24, 2004)

Reports that researchers have found new ways to string together artificial DNA bases. The techniques could aid the creation of altered genetic material for applications in medicine and technology.

<http://www.nature.com/nsu/040223/040223-2.html>

GENE THERAPY

Gene Therapy's Twisted Path to Success

Mark S. Lesney, *Modern Drug Discovery* (March 1, 2004)

Rather than becoming an easily generalized therapy for a host of different conditions, Lesney reports that gene therapy looks likely to achieve success only when it is most individualized—to disease, to vector, and to patient.

<http://pubs.acs.org/subscribe/journals/mdd/v07/i03/pdf/304lesney.pdf>

HUMAN DIAGNOSTICS

The Quest for Complex Genes

Malorye A. Branca, *Bio-IT World* (February 18, 2004)

Most common diseases, such as heart disease, diabetes, and stroke, involve a mysterious combination of genetic and environmental influences. Branca discusses the advantages of family linkage studies, where the genomes of family members are similar.

<http://www.bio-itworld.com/archive/021804/genes.html>

NANOTECHNOLOGY

Nanopore Detection: Threading DNA Through a Tiny Hole

Tom A. van de Goor, *Pharmacogenomics Online* (March 1, 2004)

Looks at how a tiny hole called a nanopore could be an enabling breakthrough that could lead to a personalized genome ID.

<http://www.pharmacogenomicsonline.com/pharmacogenomics/data/articlestandard/ph>

armagenomics/142004/90380/article.pdf

PROTEOMICS

Proteomics Goes Cellular

Patrick Schneider, Bio-IT World (February 18, 2004)

New technologies combining the simultaneous analysis of protein expression with a broad spectrum of target tissue specimens are required for further progress in proteomics. Schneider discusses the value of tissue microarrays (TMAs).

http://www.bio-itworld.com/archive/021804/strategic_proteomics.html

11) RESEARCH TOOLS (2 articles)

GENOME SEQUENCE

Chicken Genome Is Sequenced

Edward R. Winstead, Genome News Network (March 4, 2004)

Reports on the completion of sequencing the genome of the chicken. As is now standard practice, the team also aligned the chicken genome with the human genome a way to identify previously unknown genes and DNA sequences that control genes.

<http://www.genomenewsnetwork.com/articles/2004/03/04/chickens.php>

Creatures Queue Up to Be Sequenced

Helen R. Pilcher, Nature (February 28, 2004)

Reports that researchers have lined up an opossum, four fungi, three roundworms and a beetle to have their genomes sequenced. By comparing the genomes of such species, scientists hope to learn more about human development and disease.

<http://www.nature.com/nsu/040223/040223-15.html>

12) THERAPEUTIC CATEGORY (22 articles)

CARDIOLOGY/ VASCULAR DISEASES

Possible Link Discovered Between Gene Responsible For Blood Vessel Development And ACD In Newborns

University Of Toronto, Science Daily (March 12, 2004)

Reports findings that the lungs of eNOS deficient mice share the same features as newborns with a fatal condition known as Alevolar Capillary Dysplasia (ACD). This could help develop potential therapies.

<http://www.sciencedaily.com/releases/2004/03/040312084955.htm>

DERMATOLOGY

Sunscreen could be made of DNA

BBC News (March 8, 2004)

Reports test findings that a short strand of DNA could become the sunscreen of the future. The DNA fragment works by penetrating the skin, then mimicking a response normally caused by DNA damage, which triggers DNA repair enzymes.

<http://news.bbc.co.uk/1/hi/health/3522551.stm>

IMMUNOLOGY/ INFECTIOUS DISEASES

Researchers Flip Immune System's 'On' Switch

Randy Dotinga, HealthDay (March 16, 2004)

Reports on new research suggesting that immune cells which shut down before they've finished destroying invading viruses such as HIV may have something to do with the body's need to protect itself from the havoc caused by overheated immune cells.

<http://www.healthday.com/view.cfm?id=517922>

METABOLISM/OBESITY

Japanese Vegetable Extract Offers Promise for Diabetes Control

Nutra Ingredients (March 9, 2004)

Reports that a new trial on Caiapo, an extract of white sweet potatoes taken in supplement form in Japan, confirms that it improves blood sugar and cholesterol levels in type 2 diabetic subjects.

<http://www.nutraingredients.com/news/news-NG.asp?id=50467>

NEUROLOGY

A New Hypothesis About Alzheimer's Disease

Scripps Research Institute, Science Daily (March 16, 2004)

Reports on a new theory about the cause of Alzheimer's disease: the disease arises as a consequence of inflammation, which creates abnormal metabolites out of normal brain molecules, leading to abnormal folding of amyloid beta proteins.

<http://www.sciencedaily.com/releases/2004/03/040316072210.htm>

ONCOLOGY

DNA-boosted Sunscreen May Fight Cancer

Helen Pearson, Nature (March 2, 2004)

Reports on research indications that using sun-cream containing DNA

fragments might cut the risk of skin cancer. The fragments are thought to trick skin cells into thinking that sunlight has damaged their DNA, which triggers certain protein production.

<http://www.nature.com/nsu/040301/040301-3.html>

Unusual DNA May Be Key to Cancer

BBC News (March 4, 2004)

Reports research discovery that a weakness in the structure of DNA may make some cells more likely to turn cancerous.

<http://news.bbc.co.uk/1/hi/health/3528453.stm>

Nation's First Clinically Annotated, Publicly Available Gene Expression Database to Help Researchers Accelerate Cancer Treatment Discoveries

Galen Perry, International Genomics Consortium (March 5, 2004)

Reports on project which will provide all biomedical investigators with important information on which gene activities are increased or decreased in patients' tumors, allowing multiple new approaches to the prevention and treatment of cancer.

http://www.intgen.org/expo_scientific_release.html

And When ImClone's Drug Doesn't Work...

Arlene Weintraub, Business Week (March 8, 2004)

There are likely many subtypes of colon cancer, each carrying its own set of "biomarkers." It is not always practical to collect tumor samples; new technologies are emerging that can detect proteins after being sloughed off into the bloodstream.

http://www.businessweek.com/magazine/content/04_10/b3873090.htm

The Odyssey Of A Cancer Drug

Catherine Arnst, Business Week (March 8, 2004)

Describes the long process in ImClone's obtaining the FDA's approval of Erbitux, the antibody that blocks cancer cell growth.

http://www.businessweek.com/magazine/content/04_10/b3873087.htm

New Insight on Cell Growth Could Lead to Method for Stopping Cancer

Chad Boutin, Purdue News (March 29, 2004)

By investigating a single molecule that influences cell growth, a research group in the Purdue Cancer Center has gained new insight into the chain of events that make some cancer cells divide uncontrollably.

<http://news.uns.purdue.edu/UNS/html4ever/2004/040328.Henriksen.ras.html>

Genasense Faces Identity Crisis

Malorye A. Branca, Bio-IT World (February 18, 2004)

Discusses the controversy over different theories of antisense therapy's mechanism. Table of the 8 companies with antisense compounds, their

targets and clinical trial phase.

http://www.bio-itworld.com/news/021804_report4453.html

Tumor Suppressor Genes Predict Bladder Cancer Future

Baylor College Of Medicine, Science Daily (March 18, 2004)

Reports on the roles of 4 gene alterations in the tumors of 80 bladder cancer patients, finding that one of the genes was altered in 83% of patients. Two mutated genes indicate that there is a high risk that the cancer will continue grow and spread.

<http://www.sciencedaily.com/releases/2004/03/040317073445.htm>

Researchers Find A Protein That Controls Cell Growth, Offers Possibility Of Finding New Cancer Therapies

New York University Medical Center And School Of Medicine, Science Daily (March 11, 2004)

Reports on a protein called APC which helps control the premature entry of a cell into the S phase of the cell cycle, a potential cause of genetic instability, which in turn can propel a cell into uncontrolled proliferation, resulting in cancer.

<http://www.sciencedaily.com/releases/2004/03/040311074719.htm>

'Switched-Off' Genes Put First Chink In Colon Cell's Anti-tumor Armor

Johns Hopkins Medical Institutions, Science Daily (March 15, 2004)

Reports on how inactivated genes, called SFRPs - for secreted frizzled-related protein - put the brake on a pathway of cell-growth genes that is an early step en route to cancer.

<http://www.sciencedaily.com/releases/2004/03/040315071202.htm>

Search for Colon Cancer Genes Pays Off

Edward R. Winstead, Genome News Network (March 11, 2004)

Reports on "hotspots" which could be added to tests that identify cancerous mutations using DNA from stool samples. DNA tests provide less information than a colonoscopy but are not invasive.

http://www.genomenewsnetwork.com/articles/2004/03/11/colon_cancer.php

Key to Deadly Form of Skin Cancer

BBC News (March 17, 2004)

Researchers have found that 90% of malignant melanoma cells produce abnormally high levels of a protein called BRN-2. The discovery could help differentiate between melanomas and less dangerous moles.

<http://news.bbc.co.uk/1/hi/health/3516168.stm>

Pathology Goes Molecular

Thomas Baer, Bio-IT World (February 18, 2004)

New technologies, such as molecular pathology in the area of in

gene-expression-based diagnostic tests, are enabling more personalized cancer therapies. Illustration of laser-capture microdissection system for cell-specific molecular analysis.

http://www.bio-itworld.com/archive/021804/strategic_pathology.html

OPHTHALMOLOGY

NIH Researchers Discover Promising New Therapy for Blinding Eye Disease

Tom Hoglund, National Eye Institute (March 1, 2004)

Reports on clinical trial results finding that once monthly intravenous infusions with an immune therapy drug called daclizumab controlled uveitis and was well tolerated in seven of 10 patients over a four-year period.

<http://www.nei.nih.gov/news/pressreleases/030104.htm>

Scientists 'Re-grow Optic Nerves'

BBC News (February 29, 2004)

Explains a gene therapy technique used to try to boost the growth of nerve fibers into the optic nerve by injecting a gene designed to turn the proteins that are programmed to stop re-growth off.

<http://news.bbc.co.uk/1/hi/health/3495717.stm>

OTOLARYNGOLOGY

Key Gene Identified for Development of Inner-Ear Structure Required for Balance

Joyce Peterson, The Jackson Laboratory (March 8, 2004)

Reports on discovery of a protein whose enzymatic function is indispensable for development of this balance system.

http://www.jax.org/news/key_gene_identified_for_development_of_inner_ear_structure_r.html

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