Fisher buys Dharmacon

The battle for supremacy in the reagent supplier sector heated up in February, when Fisher Scientific International (Hampton, NH, USA) acquired RNAi reagent company Dharmacon (Lafayette, CO, USA) for $80 million in cash—four months after Invitrogen (Carlsbad, CA, USA) acquired Sequitur (Natick, MA, USA), another RNAi reagent firm. The deals are a result of the increasing "use of siRNA as target validation research tools" and their growing importance as a revenue source for lab supply companies, says Doug Fambrough, a principal with venture capital firm Oxford Bioscience Partners (Boston, MA, USA). Although Fisher's $3.6 billion in estimated revenue in 2003 casts a shadow over Invitrogen's $778 million in revenue for the same year, the companies do compete with each other, says Eric Manning of Navigent Consulting (San Mateo, CA, USA). Fambrough speculates that other RNAi companies that may be ripe for acquisition as a result of technologies they possess include reagents supplier Ambion (Austin, TX, USA) and RNAi-based research services company Cenix Bioscience (Dresden, Germany). A possible suitor could be Qiagen (Venlo, The Netherlands), says Fambrough. *KH*

US Council on Bioethics under fire

More than 100 prominent US bioethicists and the American Society for Cell Biology (Bethesda, MD, USA) were among those protesting to US President George Bush about a decision by the President's Council on Bioethics not to reappoint—"to fire," critics say—two of its members. One, Elizabeth Blackburn of the University of California, San Francisco (San Francisco, CA, USA), is an expert in stem cell biology; the other, William May, is a professor of ethics emeritus at Southern Methodist University (Dallas, TX, USA). "It was only with the initial strong, personal assurances of the Council Chairman and the President that I was persuaded that the voice of science would be heard and integrated into the statements of the Council," Blackburn says, adding that it is "a matter of deep concern to me that reports of the Council fail to live up to the standards of scientifically defensible and intellectually balanced documents"—implying that such standards cannot be achieved if the council fires scientists. Amid this controversy over membership on the Council, researchers say that continuing controversy and restrictions have helped to slow research progress as well as retard investments, thus discouraging some biotech companies from continuing their efforts in this field. *JLF*

Mendocino bans GM

Mendocino County (CA, USA), located 130 kilometers north of San Francisco, became the first US county to ban the rearing of genetically modified (GM) plants or animals within its borders. The move could set a precedent that may do far-reaching damage in the agbiotech industry if other regions follow suit. The initiative, approved by 56% of voters on March 2nd, will probably not have any effects on GM crops such as corn, cotton and soybean grown in other parts of the country, but could potentially affect the future use of GM crops for niche products such as fruits and vegetables not grown in bulk, according to Michael Rodemeyer, executive director of the nonprofit research group Pew Initiative on Food and Biotechnology (Washington, DC, USA). Although little or no GM crops are grown in Mendocino, the move could embolden other counties and towns to introduce similar measures, says Rodemeyer. Indeed, other counties in northern California, including Marin, Humboldt and Sonoma, have also expressed interest in ballot initiatives. And on March 10, the Vermont senate passed the Farm Protection Act (S164), meant to hold biotech companies liable for unintended contamination of conventional or organic crops by GM materials. The Vermont house of representative has yet to vote on the proposed bill. *KH*

New US ES cell centers

The future of stem cell research in the United States got a major boost in February with the creation of non-federally-funded research centers in the state of New Jersey and at Harvard University (Cambridge, MA, USA). To circumvent President Bush's embryonic stem (ES) cell policy, which prohibits federal funds from being used to create new ES cell lines, both New Jersey and California have legalized ES cell research in their respective states. Now, New Jersey governor James McGreevey hopes to launch the New Jersey Stem Cell Institute (New Brunswick, NJ, USA), which is expected to receive approximately $50 million from the state and private sources over the next five years, if approved by state legislature. Harvard also has plans for a stem cell institute that will piggyback on research by Harvard professor and future center director Doug Melton, who in the March 3 online *New England Journal of Medicine* reported creating 17 new human ES cell lines. Meanwhile, in California, a coalition of scientists and patient advocacy groups are trying to collect enough signatures to get a $3 billion stem cell research funding bond on the November 2004 ballot. These states will attract top researchers, says neuroscientist Wise Young of Rutgers University (New Brunswick, NJ, USA). *KH*

UK OK's GM maize

The UK government has granted permission, on Tuesday March 9, for commercial cultivation of a single variety of genetically modified forage maize that could be planted next year. The authorization, for Bayer's LL-Chardon variety already approved in the European Union (EU), is the UK's first since the EU adopted a moratorium on commercial cultivation of GM crops in 1998. Environment minister Margaret Beckett noted that the decision was linked to field trial results published last October showing that GM maize causes few environmental problems (*Nat. Biotechnol.* **21**, 1418–1419, 2003). But the minister warned that any damage caused by GM crops to neighboring land or crops, particularly organic crops, must be compensated for by the party responsible. A spokesman for the industry-backed Agricultural Biotechnology Council (London) says the industry will carry out a consultation to ensure that "proportionate coexistence measures" are introduced. Meanwhile, GM opponents such as the Friends of the Earth are threatening to object to LL-Chardon's inclusion on the official list of cultivable seeds. *PM*

News in brief written by David Cyranoski, Emma Dorey, Jeffrey L. Fox, Ismael Gaona, Ken Howard, K.S. Jayaraman, Hepeng Jia, Peter Mitchell, Cormac Sheridan and Aparna Surendran.

US trial lacks consent

At least two trauma centers in the United States have signed on to Northfield Laboratory's (Evanston, IL, USA) phase 3 clinical trials of PolyHeme, a blood substitute, despite concerns about the lack of patient consent. The company expects up to 20 trauma centers will enroll 720 patients to complete the trial within a year. PolyHeme will be given to trauma patients during transport in ambulances and then for a 12-hour post-injury period in the hospital. Although each trauma center's institutional review board has to give approval before each trial, many eligible patients may be bleeding or in shock and thus unable to consent. US federal regulations allow exceptions to informed consent requirements in life-threatening situations. But Arthur Caplan, chair of the University of Pennsylvania School of Medicine (Philadelphia, PA, USA), is skeptical: "I am not convinced this is the only way. You could offer PolyHeme to people in emergency rooms," when they could give consent, he says. But Northfield has "previously documented the life-saving capability of the product in emergency room," says Steven Gould, its CEO. "The goal is to demonstrate an improvement in survival in bleeding patients when blood is not available," he adds. Baxter Healthcare (Deerfield, IL, USA) stopped a trial of the blood substitute HemAssist in 1998 because of higher-than-usual death rates. *AS*

EMEA speed matches FDA

The approval time of the European Agency for the Evaluation of Medicinal Products (EMEA; London, UK) for new biopharmaceuticals is now on a par with that of the US Food and Drug Administration (FDA; Rockville, MD, USA). According to an analysis from the Tufts Center for the Study of Drug Development (Boston), which examined the approval process for 26 biotech products during 2000–2003, the average EMEA approval time for biotech drugs was 17 months, compared with 16.7 months for the FDA. But the study identified bottlenecks when companies are required to respond to questions raised by the EMEA and during final approval by the European Commission (Brussels). According to Milan-based consultant Kathy Redmond, the Tuft's study may flatter the EMEA because of an overall drop in applications during the period under consideration combined with particularly lengthy FDA review times for a number of products in that time. *CS*

Rules debated on implementing the Cartegna Protocol

David Cyranosky

New rules for implementation of the Cartagena Protocol, which aims to ensure the safe handling of living modified organisms shipped across borders, were discussed at the first protocol members' meeting in Kuala Lumpur on February 23–27. The rules were immediately denounced as unrealistic by agriculture trade associations. The protocol members agreed on recommendations for compulsory documentation accompanying exports to include information such as the "transformation event code" of the living modified organisms and the commercial name of the variety. "The requirements could include a thousand varieties," says Ron Heck, president of the American Soybean Association (ASA; Saint Louis, MO, USA). "We'd have to document all those or the shipment might be turned back." Moreover, Jerry Slocum, who represented the Corn, Soy, Cotton Coalition (Washington, DC, USA), denounced the "zero adventitious presence" tolerance of the new rules. This means that even the presence of one undocumented kernel of genetically modified (GM) corn stuck in a shipful of GM soybeans could be used to turn back a whole ship. "It's not practical, nor possible," says Slocum. The 87 parties to the protocol, which does not include any of the major GM crop exporters (US, Canada, Argentina), will implement national systems before 11 September 2005. Further clarification will come from a second meeting scheduled in Germany later this year, where the US delegation may not be invited. *DC*

Avastin approved

Shares of Genentech (S. San Francisco, CA, USA) jumped 7% on February 26 when the US Food and Drug Administration (Rockville, MD, USA) approved the therapeutic antibody Avastin (bevacizumab) as an adjunct treatment for metastatic colorectal cancer. The product is the first in the new class of angiogenesis inhibitors and works by blocking the protein vascular endothelial growth factor (VEGF), throttling tumors' blood supply. Avastin could address the 150,000 new cases of colorectal cancer diagnosed every year. The drug will cost an estimated $44,000 per year, which could generate sales of $600 million in the first year alone and eventually as much as $2.6 billion, says biotech analyst Eric Schmidt of investment bank SG Cowen (New York). "With Avastin, Genentech has highly visible revenue growth for another five years," he adds. Genentech is thought to have a three-year head start over its 30 competitors in the anti-angiogenesis arena. And the company's pipeline includes a number of other potential blockbusters: Tarceva, a small-molecule endothelial growth factor receptor blocker now in phase 3 trials for cancer; Lucentis, another VEGF-inhibiting antibody, now in phase 3 for acute macular degeneration; and the compound 2C4, now in phase 2 trials for solid tumors. *PM*

New product approvals

Product	Companies	Details
Avastin (bevacizumab)	Genentech (S. San Francisco, CA, USA) Roche (Basel)	On February 26, the US Food and Drug Administration granted marketing approval for Avastin, an anti-angiogenic drug to be used with intravenous chemotherapy for the treatment of patients with previously untreated metastatic colorectal cancer. Avastin is an antibody that inhibits vascular endothelial growth factor, a protein that is an important mediator in angiogenesis. Roche is partnered to market the drug outside the US if approved.

BRCA2 patent awarded

The European Patent Office (EPO; Munich) on February 11 granted the British charity Cancer Research UK (CRUK; London) a broad patent covering any activity involving the identification of mutations in *BRAC2*, one of two genes known to be linked to breast and ovarian cancer. The patent effectively breaks the monopoly of Myriad Genetics (Salt Lake City, UT, USA), which has held a limited European patent since May 2001 on the use of *BRCA2* for diagnosis and genetic screening—which is different from the broad CRUK patent. With the EPO decision, Myriad or any other commercial entity must now obtain a license delivered "under commercial terms" from CRUK before marketing *BRCA2* testing in Europe. Unless Myriad overturns the CRUK patent, other laboratories can do *BRAC2* testing without having to send all samples back to the Myriad's headquarters in Utah—a compulsory approach in force until now that is seen as undesirable by other laboratories for both financial and privacy reasons. By contrast, CRUK intends to extend its UK policy to all European public laboratories and thus grant them the right to test for *BRCA2* without paying any fees. On May 17, the EPO will adjudicate the first of these challenges, launched by France's Institut Curie (Paris), against three of Myriad's patent on a related gene, *BRCA1* (*Nat. Biotechnol.* **19**, 1004, 2001). *PM*

China reshuffles biotech

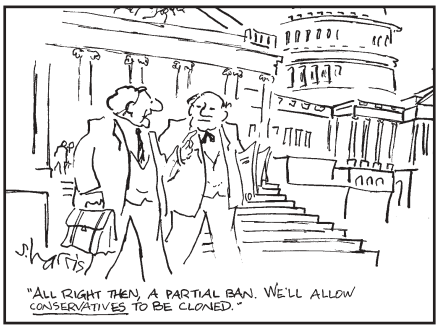
On January 18, the state-owned drug and vaccine company China National Biotec Corporation (CNBC; Beijing), originally linked to the Ministry of Health before being privatized, launched a nationwide R&D Center in Beijing in a bid to increase the rate of technology transfer of biotechnology research in the country. The R&D center will coordinate the research resources of China's six major bio-drug research institutes and will launch joint research programs involving the Chinese Academy of Sciences (Beijing, China) and the Academy of Military Medical Sciences (Beijing, China). Such programs will help transform the center's basic research fruit into marketable products, says Xiangmin Li, director of the CNBC's strategic development department. The center will first receive RMB70 ($8.45) million from CNBC in the second half of this year to contribute towards the development of vaccines against diseases such as severe acute respiratory syndrome (SARS) and AIDS. Another RMB300 ($36.23) million will be allocated next year to develop applications in genetic engineering. Yongchun Zhou of the China Science and Technology Promotion Center (Beijing, China) says CNBC's effort of integrating domestic biotechnological researches resources is necessary because, until now, China's academic biotech research has been too theoretical for pharmaceutical firms to finance the development of applications. *HJ*

Sequencer patent upheld

The Central District Court of California (Los Angeles, CA, USA) on February 17 dismissed Henry Huang's claim that he should be included as an inventor on four automated DNA sequencer patents. Huang filed a lawsuit on 19 February 2003 against the California Institute of Technology (Caltech; Pasadena, CA, USA), which owns three patents, and Applied Biosystems (ABI; Foster City, CA, USA), which owns one patent and licenses the Caltech patents. Huang was seeking to be named a co-inventor on the patents because he claims that he conceived of the idea to use optical detection and chemically tag DNA with fluorescent dyes to automate the DNA sequencing process for 'real-time' analysis. Caltech representatives admit that Huang was working with ultraviolet-light tags but say that his work failed and he left before his work could be developed (*Nat. Biotechnol*, **20**, 647, 2002). "In general, it is important for putative inventors to act early, rather than late," says Paul Fehlner, an attorney at the intellectual property law firm Darby & Darby (New York). He believes the court's decision will not influence a motion for appeal filed by MJ Research (Waltham, MA, USA), ABI's competitor, claiming that ABI had improperly obtained and licensed the patents because Huang was not included as an inventor. *AS*

EU introduces GM labels

New EU regulations governing the authorization, traceability and labeling of genetically modified food and animal feed come into effect on April 18, but not all EU member states will have required enforcement procedures in place by then. Moreover, the penalties for infringements are likely to vary, because they will be determined at national rather than an EU level. In the United Kingdom, for example, local government is in charge of enforcing the rules. Yet a 12-week consultation process set up to define penalties was not due to begin until March, according to a Food Standards Agency (London) spokesperson. The regulations will be phased-in gradually because the products that will be subject to the new rules have differing processing times and life cycles, according to a spokesman for the Agricultural Biotechnology Council (London). Greater harmonization could eventually come via a proposed regulation covering official food and feed control systems, unlikely to come into force before 2006. "This [proposed regulation] attempts to make [enforcement] an even playing field and generally to improve enforcement as a result," says Neil Griffiths, CEO of technical and legal consultants Law Laboratories (Birmingham, UK). *CS*



Andalusia's ES cell battle

The regional government of Andalusia in Spain licensed embryonic stem (ES) cell lines from the UK Stem Cell Bank (Potters Bar, UK) on March 5 and is planning to license more ES cell lines from Karolinska Institute (Stockholm). But the Andalusian authorities might be stymied by the national government. The cell lines will be held at the newly created ES cell bank in Granada and made available to scientists in three laboratories in the University Pablo de Olavide (Seville) and the University of Málaga and Hospital Carlos Haya (both in Málaga). Bernat Soria, who directs the Seville laboratory, says: "We have launched the laboratory and hired the personnel. Now we only lack the biological material, which can come [solely] from these two places [United Kingdom and Sweden] and from Singapore."Such research could suffer some delays because on January 15 the national government called on the Spanish Constitutional Court (Madrid) to rule whether Andalusia has the legal authority fund research projects using ES cells. A national law was amended in November 2003 to prohibit the import of cellular lines from abroad, and the national government in Madrid believes that a regional government has no power to authorize this type of research. The verdict is expected in June. *IG*

BioCore CEO charged

The founder and CEO of collagen wound care products firm BioCore (Silver Spring, MD, USA) has been indicted on two counts of bank fraud and conspiracy to commit money laundering. Manoj Jain and his alleged accomplices, BioCore's former VP of finance Harvey Greenwalk and Richard Cayce Sr., are said to have provided false appraisals and supporting documents to secure $4.95 million in bank loans for BioCore and its affiliates, BioFoods (Oskaloosa, KS, USA) and BioCore Medical Technologies (Topeka, KS, USA), between April 1999 and May 2000. The three of them, along with Richard Cayce Jr., are also facing charges of conspiracy to commit money laundering by transferring the fraudulent proceeds between their various companies: August Trading LLC (Fort Worth, TX, USA; owned by Cayce Sr. and Jr.), ODC Biotech International (Fort Worth, TX, USA; owned by Greenwalk and Cayce Sr.), and Aljack Sales Corp (Fort Worth, TX, USA; controlled by Greenwald). Jain initially pled not guilty on March 10, but the case is ongoing, and if found guilty the men could each face 50 years in federal prison—30 without parole for bank fraud and 20 for money laundering. BioCore first came under criminal investigation in 1997 amid allegations regarding the company's access to state funds. *ED*

Asian biotech associations to federate


FABA

A new forum, the Federation of Asian Biotech Associations (FABA), is to be established in June to help Asian biotech and academics forge business links through deals such as technology transfer agreements. India, Pakistan, Singapore, Malaysia, Thailand, Sri Lanka, the Philippines and Israel are founder members—and the list is expected to grow. "FABA would act as an apex body for biotech companies across Asia and all biotech associations would become part of it," said Bhim Sain Bajaj, chairman of the Southern branch at the All India Biotech Association (AIBA; New Delhi). FABA will help its members become familiar with technologies available in the region through annual trade shows and foster links among industry players and between industry and academia. The federation will also act as facilitator and matchmaker, either by helping to assess the technology in a deal or by working out the best price and terms for royalty payments. "The federation is a good idea because its members will be able to better negotiate the terms between themselves than with a company in the developed world," comments Anwar Nasim, chairman of the National Commission on Biotechnology of Pakistan (Lahore). *KSJ*

Selected research collaborations

Company 1	Company 2	$ (millions)	Details
Avax Technologies (Overland Park, KS, USA)	Opisodia SAS (Lyons, France)	3	A two-year manufacturing agreement to produce biological products for clinical trials and commercial purposes. Avax subsidiary Genopoietic (Miribel, France) will provide its cell and gene therapy resources. Opisodia SAS (Lyons, France) will provide its monoclonal antibody expertise. Avax will receive $3 million.
Biogen Idec (Cambridge, MA, USA)	Celltech Group (Slough, UK)	*	A collaboration to develop antibodies against immune response regulator CD40 ligand protein used in the treatment of autoimmune diseases. Celltech will identify and produce new antibodies and will pay development costs through phase 1 clinical trials. After phase 1, Biogen Idec has the first option to co-invest in product development.
Caprion Pharmaceuticals (Montreal, Canada)	Abbott Laboratories (Abbott Park, IL, USA)	*	A deal to discover antibody targets and develop therapeutics for lung cancer. Caprion will quantitatively profile plasma membrane proteins of cells by comparing normal and disease conditions. Abbott will evaluate non-exclusively drug targets for non-small-cell lung cancer and additional targets that Caprion discovers in the future.
Aventis Pasteur (Lyons, France)	Intercell AG (Vienna, Austria)	*	An effort to develop protein-based bacterial vaccines. Intercell will identify antigens against which Aventis Pasteur will develop vaccines. Intercell will receive up-front payments and license fees and is eligible for milestone payments and royalties. Aventis Pasteur will receive worldwide commercialization rights to any resulting products.
Pevion Biotech (Bern, Switzerland)	AlgoNomics (Ghent, Belgium)	*	An 18-month collaboration to design peptides derived from bronchiolitis-causing respiratory syncytial virus for use in vaccines. AlgoNomics will study the interaction between proteins and peptides to design peptides, which will be delivered using Pevion's virosome-based delivery platform.
Bionomics (Adelaide, Australia)	Walter and Eliza Hall Institute (WEHI ; Parkville, Australia)	*	A deal to discover drugs for the treatment of central nervous system disorders including epilepsy and anxiety. Bionomics will provide its ion channel drug discovery platform to screen WEHI's compound library. Financial details were undisclosed.
Xencor (Monrovia, CA, USA)	Eli Lilly & Co. (Indianapolis, IN, USA)	*	A collaboration to optimize the physical and biochemical properties of an unnamed therapeutic protein. Xencor will provide its technology to create variants of the therapeutic. Eli Lilly will have the option to develop drug candidates. Further financial details were undisclosed.

*, financial details not disclosed.