

nies such as Astra Zeneca and American Home Products, while providing it an even greater valuation than Aventis and Schering-Plough (see Table). And at least for now, Amgen can enjoy this elevated status without facing one of the pharmaceutical industry's ongoing headaches—patent expirations. Amgen's earliest patent expiry is that of Epogen in Europe in 2004.

Amgen's acquisition of Immunex may be distinguished from other recent biotech deals in scale, but not in objective. Eric Schmidt, biotech analyst at SG Cowen (New York), points out that almost all large biotech acquisitions to date have been "product acquisitions and not company acquisitions." Amgen will likely carve out the Enbrel component of the deal, paring off other overheads. Other recent deals follow a similar pattern: for example, on December 6, 2001, Millennium Pharmaceuticals announced it would buy cardiovascular specialist COR Therapeutics for \$2 billion in shares, almost an 80% premium (*Nat. Biotechnol.* 20, 11, 2002). The COR deal provided Millennium with a badly needed blockbuster product, the anti-clotting agent Integrilin, and a sales and marketing team. Millennium had just one drug on the market, Campath, the rights to which it recently

returned to its developer, Ilex Oncology. MedImmune likewise forked out \$1.5 billion on December 4, 2001, for fellow vaccine developer Aviron, gaining the as-yet-unapproved nasal-spray flu vaccine FluMist (*Nat. Biotechnol.* 20, 11, 2002). MedImmune had just one marketed drug, Synagis, a treatment for serious respiratory tract infections in infants, whose sales are expected to plateau, according to Lehman Brothers.

The emphasis on product-focused deals might also explain why much of the acquisition activity has occurred in the United States and not in Europe. Many more US companies have drugs in later stages of development, which make attractive targets, says Schmidt. Other companies known to be considering becoming acquirers include Chiron, Biogen, and Genentech, which have weak product pipelines. Indeed, in early January Chiron (Emeryville, CA) purchased cancer drug manufacturer Matrix Pharmaceuticals (Fremont, CA), ostensibly for access to an experimental cancer drug tezacitabine, which will move into phase II trials.

The year 2002 could see considerably greater merger and acquisition activity within the sector.

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## Maize uncertainties create political fallout

The political implications of results purporting to show that DNA from commercial transgenic crops has entered landraces of maize in Mexico are already starting to be felt, even though the issue remains unresolved scientifically. Though the political response in Mexico itself has been relatively sober and considered, the precautionary instincts of Europe's politicians may mean the loss of yet another opportunity to lift the *de facto* moratorium on commercial plantings of GM crops in Europe.

The controversy over Mexican maize stems from work performed by David Quist and Ignacio Chapela, researchers at the University of California, Berkeley, whose analyses indicated that DNA sequences presumed to have come from commercial transgenic maize had found their way into a small number of farmer-bred maize plants in Mexico. The researchers conjectured that the flow of transgenes might represent a threat to biological diversity. Their paper, published in *Nature* at the end of November after an extensive period of review and revision, stimulated environmental groups to urge governments to step up their restrictions on GM crop activity (*Nat. Biotechnol.* 20, 3, 2002).



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Such reactions reflect genuine concerns about threats to genetic diversity, especially in areas such as Mexico which, as the origin of maize-based agriculture, is the center of genetic diversity for that crop. At the beginning of December, the Mexican senate took up Greenpeace's cry and called for its Department of Agriculture to stop all Mexican imports of US corn. President Vicente Fox and his government have resist-

ed these calls. Luis Herrera-Estrella, Director of CINVESTAV Irapuato, Mexico's leading center for plant biotechnology, believes that the Mexican government will not be rushed into decisions until scientific investigations are complete. "People generally are not really worried about this and, unless there is huge amount of public pressure, the political response in Mexico will be rational," says Herrera. That is not to say that there are no implications within Mexico. Its own moratorium on commercial planting of GM materials was due to end in April 2002 but will now probably be extended, according to Herrera.

The real extent of any gene flow from commercial transgenics in Mexico is still unclear. Continuing work at the International Maize and Wheat Improvement Center (CIMMYT; El Batán, Mexico) has so far not turned up any evidence of the suspect transgenic sequence in over 40 samples from CIMMYT's gene bank. The center's latest analyses, reported in a press release in mid-December, indicated that it has also not found the promoter in 42 samples of seeds collected in 2000 from the same region, Oaxaca, in which the Berkeley researchers had operated.

At the same time, Mexican government laboratories seem to have confirmed Quist and Chapela's basic finding. A preliminary announcement was made in September by the Mexican Instituto Nacional de Ecología that landrace maize collected in Oaxaca and elsewhere contained transgenes. Although those results might have been due to contamination of the field or laboratory samples, Herrera says it looks as if at least some of the positive results were real. In other words, as widely anticipated by environmentalists and biotechnologists alike, gene flow has occurred between the various types of maize present in Mexico.

Confusingly, however, the data from the Berkeley study may be scientifically flawed, perhaps seriously. Peggy Lemaux from the Department of Plant and Microbial Biology at the University of California, Berkeley is just one of the researchers who are aware that scientists from various institutions are preparing scientific challenges to the data in Quist and Chapela's paper. "Graduate students and postdocs spotted problems with the papers," she explained. "The methods used in their paper are common practice to students, and seeing possible errors was not difficult." She believes that the arguments have scientific validity and that both sides of the story need to be heard. People are entitled to different views on the desirability of GM crops, she says, but they should start consideration of the issues from solid data. "We must address the issues brought up by the

Quist and Chapela paper head on," says Lemaux, "but our consideration of the issues should be based on solid data."

Herrera is confident that Mexico will respond appropriately to the scientific findings. The appropriate response to concerns about gene flow is not, he says, to prohibit GM maize imports, but to police the practical measures designed to minimize gene flow. Imported seed is supposed to be heat treated to prevent germination, but tests performed on mixed transgenic and non-transgenic corn that came into Mexico at the end of 2000 showed, Herrera says, that 80–90% of seeds could germinate. He points out that the government has already established an expert committee that will consider not only the impact of gene flow on landrace maize but also studies that examine the way that small-scale farmers incorporate new traits into landraces.

In Europe, the response seems destined to be less sober, and some senior European officials believe that the reported findings are likely to affect discussions at the European heads-of-state's meeting in March in Barcelona. For instance, pressure had been mounting on the leaders of European nations to discuss lifting the *de facto* morato-

rium imposed by Europe's Council of Environmental Ministers on the commercial growing of GM crops; the US has been threatening to take the European Union to the World Trade Organization over the issue, and the USDA has called on the European Commission (Brussels) to ensure that the lifting of the moratorium is on the Barcelona agenda. However, the maize story appears to have greatly diminished the chances that the moratorium will be discussed. According to one insider in the EC, the environmentalist message quickly circulated around the administration, putting officials in the research and entrepreneurial divisions of the Commission immediately on the defensive. "Anything like this has a political repercussion," said the official. "Something like the Mexican maize influences the way politicians can think about an issue."

This, in turn, may serve to undermine the impact of the Europe Union's "Strategic Vision" for biotechnology (see following story), another planned item on the Barcelona agenda. As one Commission official put it: "How can we be going forward with a positive strategy on the one hand and at the same time maintain a moratorium?"

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## EC prepares strategic vision for biotechnology

Industry associations and European governments have called on the European Commission (EC; Brussels) to ease the regulatory approval regime for biotechnology products and to push for EU-wide implementation of a revised patenting system. These and other suggestions have been considered for a new policy, the "Strategic vision on life sciences and biotechnology," drafted jointly by the EC's Secretariat General and the Enterprise, Environment, Consumer Policy, External Relations, Agriculture, and Research units. It was expected to be adopted by a commissioners' meeting at the end of January, as part of the so-called "Lisbon process" launched at the EU summit at Lisbon in 2000, which aims to make Europe a highly competitive knowledge-based economy within ten years (*Nat. Biotechnol.* 19, 1000, 2001).

Details of the new strategy were unpublished as *Nature Biotechnology* went to press. But Christian Siebert, a senior official at the EC's Enterprise Unit, told *Nature Biotechnology* it follows "a comprehensive approach of tackling all issues relevant to biotechnology—regulation, research, competitiveness, public opinion and involvement, ethics, and international matters." The most ticklish issue to be addressed is Europe's ambiguous attitude to

GM foods. The strategy declares that member states should be willing to grant marketing approval to GM foods unless there are scientific reasons to withhold it, in accordance with EU law, says Siebert. "We have to move away from the current situation where EU legislation is not being applied, in other words away from the *de facto* moratorium on GM approvals," he told *Nature Biotechnology*. "But the situation with member states is delicate, and we needed to find careful language."

The strategy also explicitly supports recent EC proposals to speed up new-drug approval times (*Nat. Biotechnol.* 19, 798, 2001). And EC funding for life sciences research has been set out: Priority will be given to exploiting the human genome, a field that will be granted €2 billion until 2006. This budget is expected to be approved by the middle of this year, says Siebert.

Other proposals address the problem of Europe's still-fragmented patent system, calling on member states to implement the 1998 biotechnology patenting directive without delay (11 out of 15 have not yet done so). It also urges rapid adoption of the so-called "community patent" system, under which companies will be able to file a single patent that is valid and enforceable in all EU member states. This

should have been adopted at the end of 2001 but agreement stalled on two issues—translation into alternative languages, and the role of national courts in community patent disputes. "It is clear what specific issues need to be resolved, though we cannot set a particular date for the adoption," says Siebert.

The strategy took into account the opinions of commercial firms, academics, and other interested parties who participated in a three-month public consultation ending in December. A total of 311 comments were submitted, of which 79 came from academic organizations, 36 from biotechnology firms and trade organizations, 50 from civic public interest groups, and 113 from individuals. Several banks also offered suggestions.

- The European Association for Bioindustries (EuropaBio) said that the European decision-making process for biotechnology product marketing authorizations "clearly lacks transparency and planning security for the industrial investor" and demanded that risk assessment and risk management be delegated to an independent body rather than being subject to political influence by member states. EuropaBio also urged faster movement towards a pan-European patent system, noting that "Filing of patent application. . . is far more bureaucratic and more expensive in comparison to Europe's most important competitors, the US and Japan, respectively." The association further asked the EC to encourage the setting up of regional centers of competence for biotechnology ("bioregions"). It suggested the launch of an EU-wide competition among regions, with member states encouraged to establish favorable starting conditions for their "incubation centers"—similar to the "BioRegio" project already carried out in Germany (*Nature Biotechnol.* 16, 614, 1998).

- Likewise, the European Federation of Pharmaceutical Industries and Associations urged the EC to push for faster adoption of the community patent system, and said that pharmaceutical legislation should be revised with the introduction of a fast-track approvals procedure. It also demanded the launch of a wide-ranging public information campaign to restore public confidence in biotechnology, together with strict new legal protections for personal genetic information.

- The UK's BioIndustry Association (BIA) echoed warnings against over-regulation. "We are concerned that the complex regulatory framework for investment, research, and product evaluation in the EU will hinder the further development of the industry." In particular, BIA warned the EC against any ban on embryonic stem cell research, insisting it was "too early" to justify such a move.

- One of the most strongly expressed comments came from the UK government, which clearly has fears that the EC's ten-year strategy