IN brief

Amgen's bone blockbuster

Amgen has announced favorable results for its experimental osteoporosis drug Denosumab that suggest it could take on market leader Fosamax, Merck's successful small-molecule drug. In phase 3 trials, Denosumab reduced by two-thirds the instance of spine fractures in postmenopausal women with osteoporosis. If the US Food and Drug Administration gives Amgen of Thousand Oaks, California, the green light to market, Denosumab will vie for a share of the market dominated by Whitehouse Station, New Jersey–based Merck and worth nearly $2 billion in 2007. Denosumab is touted as the blockbuster drug that could turn around Amgen's fading fortunes following safety concerns over its anemia drugs (*Nat. Biotechnol.* **26**, 361–363, 2008). The drug, a fully human monoclonal antibody (mAb) that regulates bone-destroying osteoclasts, achieved higher bone mineral density gains than Fosamax (alendronate) in head-to-head trials. Side-effect profiles may favor Denosumab, as the mAb does not linger in the body once treatment is stopped, unlike bisphosphonates such as Fosamax that bind to the bone. Patients have also expressed a preference for twice-yearly antibody injections over weekly oral Fosamax. But Christopher Raymond, a market analyst for Milwaukee, Wisconsin–based Robert W. Baird & Co., says: "Nobody argues that D-mab has a lot of promise and probably will be a very good product. It's just it might not be enough for Amgen." Denosumab is currently under investigation as a therapy for other conditions that reduce bone density, including rheumatoid arthritis and breast cancer. *–Hayley Birch*

Enbrel patent feud

The University of Iowa and University of Iowa Research Foundation (UIRF) are suing Amgen, of Thousand Oaks, California, for patent violation. According to the complaint, Amgen and its affiliates "have for many years infringed the Iowa Patents with full knowledge of them" to produce Enbrel (etanercept) and Vectibix (panitumumab). UIRF-owned patents 5,168,062 and 5,385,839, filed in 1992 and 1995, respectively, protect the human cytomegalovirus promoter—a key regulatory sequence used to increase protein expression and enhance the production of biologic therapeutics. Enbrel, a recombinant fusion protein that blocks tumor necrosis factor, is used to treat rheumatoid arthritis and psoriasis, and generated $1.69 billion in US sales for Amgen in the first half of 2008. Vectibix, a monoclonal antibody used to treat colon cancer, generated $57 million over the same period. Amgen has ignored entreaties to license the technology, the complaint also states. Michael Shuster, a patent attorney for Mountain View, California–based Fenwick & West, says the case may have only been filed now, despite years of alleged patent violations, because the university was "probably trying to negotiate a license with Amgen and trying to establish a successful licensing record." UIRF has granted 113 active licenses for these patents. Immunex, a subsidiary of Amgen, also located in Thousand Oaks, California, is a co-defendant in the case. Amgen denies any wrong-doing. *–Asher Mullard*

Agency rushes to redraw plant biotech rules

The rules for release and transport of genetically engineered (GE) plants are being overhauled for the first time since 1987**?**. Early in October, officials at the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposed new regulations under the Plant Protection Act of 2000.

Agency officials say the proposed changes would "improve and clarify" procedures that lead APHIS to "approve" GE plants by granting them "nonregulated status." The current system allows companies or universities developing certain exempted classes of GE plants to notify USDA rather than apply for permits. Under the new rules, submission practices would be more uniform, though possibly more burdensome.

APHIS is receiving public comments until November 18. But critics complain that the proposals, which met little public fanfare, leave little time to respond. The debate about these proposals is "too important" to disenfranchise American farmers from it, says Bill Wenzel, director of the Farmer-to-Farmer Campaign on Genetic Engineering, based in Madison, Wisconsin, and a member of a broader national coalition of farm groups. Noting that many US farmers are busy "harvesting crops," he urged APHIS to extend the comment period to 120 days.

Provisions allowing crops that produce pharmaceuticals to be grown in fields are under fire, as they might mingle with foods that are sold to consumers. Meanwhile, other critics say that the proposals do not go far enough, as they fail to reduce regulatory burdens. Drew Kershen of the University of Oklahoma Law School in Norman, Oklahoma, calls on APHIS (and other federal agencies) to "abandon its unjustified and discriminatory bias against agricultural biotechnology" and to regulate such crops "in a manner no different than…crops from any other breeding method." *Jeffrey L Fox*

level by the Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals. Codex is sponsored by the United Nations and sets food safety standards internationally.

For biotech companies submitting products or animals for agency review, this FDA draft guidance "clarifies" the procedures, says Barbara Glenn, who is Managing Director for Animal Biotechnology at the Biotechnology Industry Organization (BIO) in Washington. In making related FDA regulatory processes more explicit, it will boost both consumer and investor confidence in the companies working in this sector and the products they are developing, she says. The reference to international guidelines is a further boon. "BIO considers it significant that FDA is aligning [the guidance] with Codex, which will be widely used by other countries."

The potential for duplication, however, worries some companies. "We're concerned that the guidance doesn't lay out procedures for collaborations within FDA," says Eddie Sullivan, who is COO at Hematech in Sioux

SELECTED research collaborations

Partner 1	Partner 2	$ (millions)
Maxygen (Redwood City, California)	Astellas (Tokyo)	170
GlycArt (Schlieren-Zurich)/Roche (Basel)	Genentech (S. San Francisco, California)	*
Bayer Innovation (Leverkusen, Germany)/ Icon Genetics (Munich)	Kentucky Bioprocessing (Owensboro, Kentucky)	*
Bayer Innovation (Leverkusen, Germany)/ Icon Genetics (Munich)	Nomad Bioscience (Munich)	*
Athera Biotechnologies (Stockholm)	Dyax (Cambridge, Massachusetts)	*

* Financial details not disclosed.