

kept in backyards. To disseminate bird-flu warnings more widely, the government is now translating data sheets in Lao into languages of ethnic minorities, including the Hmong and Khmu. Laos's diverse ethnic groups "pose a huge challenge for risk communication," says Castellán.

Last December, Castellán worked with FAO to train health workers in the Laotian hinterlands, including Champasack, a high-risk province bordering Thailand and Cambodia that was hit hard in 2004. "This is where the rubber hits the road,"

he says. Their messages were simple: Raise chickens, ducks, geese, and other poultry separately, sell live poultry separately from processed poultry products, and practice good personal hygiene.

However, "it's very difficult to change the minds of farmers," says San. For example, rural Cambodians have no fear of eating chickens that die of Newcastle disease. In unvaccinated flocks, this virus has a mortality rate exceeding 50%, rivaling that of H5N1. "It's hard to distinguish between Newcastle and avian influenza"—

even for a veterinarian, says San. The best strategy, he says, is to insist that chickens that succumb to disease are buried, not eaten. "We're trying to train the village health workers to put a stop to that," San says.

Transforming rural lifestyles "won't happen overnight," Castellán says. But on the front lines of Southeast Asia, the battle to stave off a pandemic flu strain is likely to be won or lost not in the cities, but down on the family farm.

—RICHARD STONE

INTELLECTUAL PROPERTY

What Good Is a Patent? Supreme Court May Suggest an Answer

Two cases raise fundamental questions about the scope of a patent and the right balance between protecting innovation and hindering commerce

Next month, the Supreme Court will hear two cases that could punch holes in a strong patent regime credited with fostering the remarkable growth of the U.S. biotechnology industry. Experts predict that the high court may rein in a specialized lower court that has shaped U.S. patent policies for the past 2 decades. At a minimum, the court's involvement reflects a world increasingly dependent on intellectual property.

The two cases pose key questions about what can be patented and the force a granted patent should have in the marketplace. In *Laboratory Corp. v. Metabolite*, a case involving two makers of diagnostic blood tests, the high court will probe the limits of patenting basic scientific principles. In *eBay v. MercExchange*, the court could rule on how much a patent holder can interfere with the activities of a company or organization infringing on its patent. (A third case up for review this spring would give the court a chance to decide how obvious a proposed invention must be to be denied a patent.) Together, the cases could have "major, major impacts" on existing patents and future applications in a range of disciplines, says former U.S. commissioner of patents Nicholas

Godici of Birch, Stewart, Kolasch & Birch LLP, based in Falls Church, Virginia.

The cases come amid calls for reforming a system bogged down by questionable patents and expensive lawsuits. Although a 2004

report by the National Research Council of the National Academies concluded that the system "does not require fundamental changes," it warned that further deterioration of patent quality could "impede research progress" and discourage innovators from "invent[ing] and disseminat[ing] technology." Last year, Congress took up the issue, but disagreements over patent quality and the appropriate use of injunctions against violators derailed proposed legislation (*Science*, 17 June 2005, p. 1725).

The framers of the U.S. Constitution included patents as a way "to promote the progress of science." For nearly 2 centuries, the United States has had some of the strongest patent rights of all nations. But since the founding of the specialized Federal Circuit appellate court in 1982, the system has struggled to find the best way to protect discoveries in biotechnology, information technology, and other emerging fields.

Because the Supreme Court rarely intrudes on the appellate court's turf on major issues, patent lawyers say its decision to accept the two cases suggests that the justices might want to step in and review how far the lower court has gone. But some patent lawyers turn queasy at the thought of having nine "outsiders" take on the system. "They think the [Federal Circuit] needs to be tightened down," says attorney Vern Norviel of Wilson, Sonsini, Goodrich & Rosati in Palo Alto, California. Under a worst-case scenario, says Kevin Noonan of McDonnell, Boehnen, Hulbert & Berghoff LLP in Chicago, Illinois, the court's upcoming rulings could imperil "thousands of [granted] patents" and "harm innovation."

Can you patent nature?

The first case centers on defining what is a natural phenomenon and, therefore, not patentable. Metabolite has rights to a patent for measuring blood levels of the amino acid homocysteine, but the patent also covers use of the test to infer levels of vitamins B-12 and B-6, which help break down homocysteine. In 1999, Metabolite and another company sued Laboratory Corp.—called LabCorp—for patent infringement and breach of contract. A



jury found LabCorp guilty of both offenses and awarded Metabolite \$4.7 million in damages. The Federal Circuit upheld the judgment on appeal, further adding that doctors who use homocysteine levels to deduce vitamin B levels, regardless of the method they use, “directly infringe” Metabolite’s patent each time they order the test and interpret the medical implications.

LabCorp argues that the relationship between homocysteine and vitamin B is a natural phenomenon that should not be patented. Many patent lawyers expect the high court to strike down that part of the patent, but they fear that the court may also scale back the kinds of things that can be patented. They divine the court’s intention from its willingness to review LabCorp’s submitted argument that the patent’s assaying step was “indefinite, undescribed, and nonenabling” and the court’s questions submitted to the U.S. solicitor general last year on whether Metabolite’s patent should have been “invalid because one cannot patent ‘laws of nature, natural phenomena, and abstract ideas.’”

Physicians believe the assaying-correlating step of the patent is invalid and fear that judicial approval of such a step would open the floodgates to other spurious patents. Such patents “operate to chill, not to promote, the progress of science ... [and] the sound practice of medicine,” wrote a coalition of medical societies, including the American Medical Association, in an amicus curiae brief to the high court. In another brief, Affymetrix, the Santa Clara, California-based gene array maker, urges the court to strike down the correlating part. Metabolite’s brief warns that the wrong decision could disqualify drug patents because it would mean the inventors “merely discovered that certain chemicals interact with the human body in ways directed by chemistry.”

Although many attorneys think that examiners went too far in awarding a patent on the correlating step to Metabolite, they worry that any corrective action by the high court will set a new and restrictive precedent. That could upend Federal Circuit decisions allowing patents on business methods, software, or biotechnology not spelled out in the aged patent laws. That would be a mistake, argues Hal Wegner of Foley and Lardner LLP in Washington, D.C., noting in a recent essay that future technologies “require an open door to patent eligibility” to win backing from Wall Street.

Parts of the biotech industry would be likely to feel the pinch from a restrictive court ruling, says Norviel. A growing roster of firms

rely on test-plus-correlate claims for gene expression tests, including Genomic Health in Redwood City, California. Another is those that have developed methods of detecting cancer or other diseases. Such innovations won’t be developed “if that sort of relationship is not patentable,” says Norviel.

The power of a patent

One week after LabCorp, the justices will hear a case that tests whether a company found to infringe another’s patent should automatically

may be caught infringing a patent. But communication and software lawyers—including those who represent RIM, the Canadian maker of the popular Blackberry e-mail device now facing patent woes—say that the threat of an automatic injunction gives too much leverage to companies seeking licensing fees for insignificant patents that they have acquired on the open market. They would like the courts to limit injunctions on behalf of these so-called patent trolls. The same issue scuttled the negotiations last year on the House reform bill.

In its brief, eBay argues that the Federal Circuit has overstepped its authority. A 1908 Supreme Court ruling that a company need not commercialize an invention to receive an injunction, it said, should be overturned if it “precludes equitable discretion.” If the high court agrees, say some patent experts, university researchers may find it harder to collect licensing revenue from their inventions if they don’t commercialize them. Also, says Noonan, “Small biotech Davids need injunctions to fight big company Goliaths.”

Advocates who believe the patent system needs tweaks but not wholesale changes hope the high court treads lightly in these fundamental areas. Richard Taranto of Farr and Taranto in Washington, D.C., forecasts

“modesty” by the court in deference to its inexperience. But Joshua Sarnoff of Washington College of Law at American University in Washington, D.C., speculates that the court may be interested in a major reform of the legal framework the Federal Circuit has created. He cites the fact that the high court ignored pleas by the U.S. government not to take the LabCorp case. Yet patent attorneys are also mindful of a 2002 decision involving cylinder manufacturers in which the high court expanded the rights of patent holders by reversing the Federal Circuit on an issue related to similar inventions.

The justices are expected to rule on both cases before the end of their current term in June. But that may not be their final word on patents. This spring, the high court is expected to decide whether to accept a case involving yet another fundamental patent issue: how high to set the obviousness bar for inventions. That can be a crucial factor in determining whether a new technology receives a patent. Fans of the status quo hope the court decides not to take the case, involving brake mechanisms. If it does, arguments will be heard in the fall.

—ELI KINTISCH



LabCorp v. Metabolite

Originally filed: 1999

Oral arguments: 21 March

At issue: Patenting scientific principles



eBay v. MercExchange

Originally filed: 2001

Oral arguments: 29 March

At issue: Power of a patent holder to halt an infringer’s business

Setting the bar. The U.S. patent community is abuzz over a pair of cases to be heard next month by the Supreme Court.

be stopped from further use of that patent. The eBay case pits the \$55-billion-a-year online auctioneer against MercExchange, a small Virginia company that had patented some online auction methods beginning in 1998 but failed to commercialize them.

In 2003, a jury found eBay to be infringing on a patent for an auction method and awarded MercExchange \$35 million. Such a ruling usually leads to a court-mandated prohibition of the use of an invention by the infringer, a disruption that would have cost eBay much more than the damages levied by the jury. But the court denied MercExchange’s request for an injunction, citing a 1954 law that allows courts to reject requests for injunctions if they do not follow “the principles of equity.”

Early last year, the Federal Circuit Court disagreed and said the lower court should have given MercExchange the injunction. Such injunctions should be the “general rule,” it opined, barring an “exceptional” public need such as a medical emergency. That ruling divided the high-tech community. Biopharma attorneys welcomed the decision, noting that the near certainty of an injunction is a big disincentive for generic drugmakers to go into production if there is a chance they

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