IN brief

GSK bird flu vaccine

The European Commission has just approved the prepandemic vaccine Prepandrix from GlaxoSmithKline, making the London-based company the first to receive the go-ahead to market. Novartis of Basel, on the other hand, recently withdrew a marketing application for its own prepandemic flu vaccine, Aflunov. The European Medicines Agency's Committee for Medicinal Products for Human Use asked for more data but Novartis could not supply this within the time frame required. Prepandrix provides protection against current H5N1 strains and would be used before and in the early stages of a pandemic. The US government has placed an order for Prepandrix, as have Switzerland and Finland. But a new version of the bird flu virus has been found that could also spark a pandemic: the H7N2 strain, which spreads rapidly among mammals. In the event of a pandemic caused by an H5 viral strain, the prepandemic H5 vaccine may offer a degree of cross-protection, but if the virus is from another family, such vaccines are unlikely to be effective, says Nick Phin, consultant in health protection at the UK's Health Protection Agency. The World Health Organization (WHO) is not planning to stockpile the prepandemic vaccine. "We don't know if the next pandemic will be caused by H5N1, H2, H7 or H9 virus," says Marie-Paule Kieny, the WHO director for initiative in vaccine research. *–Susan Aldridge*

Cabilly patent finale

An infamous intellectual property battle ended in late May when Genentech and MedImmune settled a lawsuit regarding the validity of Genentech's Cabilly 2 patent, a method for producing therapeutic antibodies. The patent remains valid, allowing the S. San Francisco–based company to continue reaping royalties—which in 2007 exceeded $133 million—from successful drugs such as MedImmune's Synagis (palivizumab). The settlement in part reduces Gaithersburg, Maryland–based MedImmune's risk of jeopardizing its relationship with Genentech. "There are only a small number of big biotech companies and you may need to license things from them in the future," says Stephen Albainy-Jenei, an attorney with Frost Brown Todd in Cincinnati. Under the terms of the agreement, MedImmune, now owned by London-based AstraZeneca, can in the future obtain licenses under the Cabilly patent family for certain products in its pipeline. The lawsuit may be over, but its repercussions are not. Before the settlement, the case had reached the Supreme Court, where a fundamental precedent in intellectual property law was revised. The Court ruled that a licensee can at the same time pay royalties on a patent and sue to invalidate it. That ruling stands, and experts say other licensees may still use it as leverage to renegotiate their contracts (*Nat. Biotechnol.* **25**, 264–265, 2007). Separately, Genentech also faces a reexam of Cabilly 2's validity by the US Patent and Trademark Office (*Nat. Biotechnol.* **26**, 362, 2008). *–Emily Waltz*

UK strong arms industry over drug pricing

The UK pharmaceutical and biotech industries are claiming success in their negotiations with government over drug prices, although the deal is less than propitious. An immediate price freeze is to be followed by an across-the-board 5% price cut starting in January 2009. For biotech companies trying to launch high-value biologic blockbusters, quicker introduction of new medicines remains the main negotiating goal. But in negotiations thus far the government has conceded only the vaguest of promises to encourage faster approval and uptake of new medicines by the state-controlled National Health Service (NHS).

Aisling Burnand, chief executive of the London-based UK Biotechnology Industry Association, is upbeat about the deal that could set a price benchmark for other European countries to follow.

The pharmaceutical and biotech industries are smarting over the UK government's strong-arm tactics but are putting a brave face on matters, probably because they have escaped with a price cut of only 5% instead of the 10% originally put on the table by ministers. "Pharma and biotech have ended up with a lot better deal than might have been thought at the beginning," says Aisling Burnand, chief executive of the London-based UK Biotechnology Industry Association (BIA). Moreover, she says, biotech companies have been buoyed by the government's willingness to leave initial pricing for new medicines in the manufacturers' hands.

For the past several years, drug prices in Britain have been controlled by an indirect method called the Pharmaceutical Price Regulation Scheme (PPRS). Under this framework, companies set their own price when launching a new drug, but have only a limited capacity to make further price increases. The scheme also places a ceiling on profits. Any company that exceeds its permitted profit cap has to refund the excess to the state-run NHS.

Last year, this system came under heavy fire from official bodies, in particular the Office of Fair Trading, an independent watchdog organization set up by government, who claimed the PPRS had not held down drug prices sufficiently and should be replaced by a system in which the NHS pays for medicines according to their therapeutic value. At the same time, GlaxoSmithKline of Brentford, UK, rashly brought a case against the government, claiming it had been unfairly treated over demands for a 4.5 % price cut on one of its drugs, Zantac (ranitidine). GlaxoSmithKline won its day in court, but the victory was short lived. Soon afterward the government unilaterally terminated the PPRS and said it was looking to negotiate a new 'value-based pricing' system, meaning considerably lower prices.

In June, a provisional 'voluntary' agreement was announced, setting a 5% headline price cut. "It's clear that the government wanted these cuts as soon as possible, and that's what this so-called voluntary scheme gives them," says Ian Oliver, senior manager of assurance practice at industry consultants Ernst & Young located in Reading, UK. There were only vague promises of an 'innovation package' under which genuinely new medicines may in future get quicker approval. "[Government officials] have the short-term fixes they wanted, and in return the industry has a degree of stability. But the innovation package is for the longer term while the price cuts are now," he adds.

The biotech industry is pinning its main hopes on a promised package of NHS measures to encourage its doctors to prescribe new medicines sooner. The so-called 'single horizon scanning' process will allow local payer bodies (called primary care trusts or PCTs, similar to a US health maintenance organization) to budget for new medicines well in advance. With this early warning system, PCTs will be allocated sufficient funds to implement National Institute for Health and Clinical Excellence (NICE) recommendations immediately and without qualification, instead of ignoring them as they do now.

Despite occasional rows like those over Avastin (bevacizumab) and Aricept (donepezil), which were deemed insufficiently cost effective, the industry is resigned to NICE's