

cases, software companies want to make things harder for those claiming infringement, whereas the biotechnology and pharmaceutical industries want to make it easier.

Despite these areas of dispute, Mossinghoff says he thinks a bill could be passed next month, before Congress packs up for the year. Nicholas Godici, another former PTO commissioner who also now works as a patent lawyer near Washington DC, says there is "a 50-50 chance" that the bill will pass either this year or next.

But the bill won't set funding for the over-worked PTO. As the number of patent applications increases, the office is stretched to its limit, and some observers say that the quality of patent decisions is suffering as a result. The PTO calls the situation a "workload crisis" in its strategic plan, but denies that its standards are dropping. "Questions of bad quality are overblown and anecdotal," claims Brigid Quinn, a spokeswoman for the PTO.

If there was single filing and examination of patents for the United States, Europe and Japan, the strain in each region would be considerably reduced. "The three major offices in the world are beginning to buckle under the workload, so we really have to get cooperation," says Mossinghoff. "This deep harmonization will remain theoretical until we get first-to-file in the United States."

Failure of the US bills would spell trouble on that front, declares Eugen Stohr, head of international affairs at the European Patent Office in Munich, "because then the rest of the world will know that the United States is not able to move to first-to-file — and that discussions on deep harmonization are useless". ■

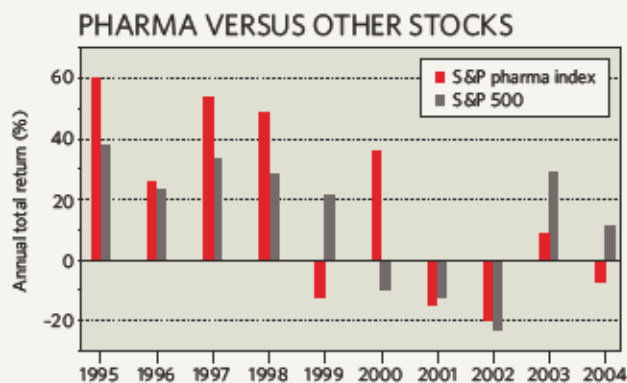
IN BRIEF

WAR ON WORDS The United States' biggest book publishers are taking the Google Internet search engine to court, charging that the web wizard's plan to scan their products and put them online (see *Nature* 433, 446; 2005) would breach copyright rules. The Association of American Publishers filed suit in the US District Court in New York on behalf of five major publishers, including McGraw-Hill and John Wiley, after talks with Google broke down. In a statement, the California-based company called the suit "short-sighted".

TB DRIVE A foundation backed by Microsoft boss Bill Gates has announced a partnership with drug manufacturer GlaxoSmithKline to expedite trials of a tuberculosis vaccine. GSK Biologicals of Rixensart, Belgium, is already conducting clinical trials of a recombinant protein vaccine that seems to induce strong, long-lasting immunity to the disease. The Aeras Global TB Vaccine Foundation will provide up to \$13 million over two years to help speed up the trials. Last year the foundation, which aims to develop an effective vaccine for tuberculosis within ten years, received \$83 million from the Seattle-based Bill and Melinda Gates Foundation to support its work.

FRAUD SQUAD A subsidiary of the Swiss biotechnology company Serono is to pay the US government \$704 million to resolve criminal charges and civil allegations related to fraudulent marketing of Serostim, a drug that treats the wasting induced by AIDS. Serono has pleaded guilty and last week agreed to pay a \$137-million criminal fine and \$567 million to settle civil allegations that it defrauded the Medicaid programme for poor people and the Medicare health insurance scheme by using illegal means to boost sales of Serostim between 1996 and 2004. The settlement is the largest ever in a Medicaid fraud case.

MARKET WATCH



Pharmaceutical stocks have seriously underperformed on the general US stock market for the past two years, as the sector loses some of its cachet. In 2003, for example, when the broadly based Standard & Poor's 500 index (S&P 500) produced an annual return of 29%, pharma managed less than a third of that. Last year, pharma actually lost ground while general stocks showed a return of 11%.

Why the fall? Experts chalk it up to a dearth of new drug approvals, compounded by liability problems faced by some major drug companies. A report by the international KPMG consultancy last month noted that, in 1998, only one out of 18 of the largest drug and medical-device makers disclosed a risk that their

pipeline of new products would not deliver. In 2003 this figure was 13.

KPMG also found that investments in pharma stocks carried more risk than other S&P 500 stocks. Their typical year-on-year change in cash flow as a percentage of assets, for example, was twice that for the market as a whole. In exchange for this risk, investors expect higher returns. But as the graph shows, they're not getting them.

Garret FitzGerald, who tracks industry trends at the University of Pennsylvania, Philadelphia, predicts that the drug sector will undergo marked structural changes in the next few years. He thinks firms able to exploit the promise of individually tailored drugs will fare best. ■

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