IN brief

Patent reform on the brink

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Patent reform on the brink!

Congress stands poised to introduce dramatic changes to US patent law, switching from a first-to-invent to a first-to-file system. Late in June the House of Representatives passed its version of the American Invents Act (H.R. 1249), following similar actions of the Senate, which passed its patent reform bill last March. Despite this momentum, the two bills are sufficiently different to require negotiation and reconciliation—raising a whiff of doubt about the ultimate success of these reform efforts. One promising sign is that US Senate Majority Leader Harry Reid of Nevada announced that the Senate will take up patent reform on the first day back from its August recess. He urges the Senate to adopt the House bill, a procedural step that aims at simplifying reconciliation of their differences, but which also risks obstructionism. One key attraction of the House bill is that it incorporates a political compromise permitting the US Patent and Trademark Office (USPTO) to fund its activities in part through revenues from fees that it collects. Those provisions are "necessary to prevent user fees collected from patent and trademark applications from being redirected to other non-USPTO purposes," according to the Biotechnology Industry Organization (BIO) in Washington, DC. More generally, both versions of this reform legislation would move the US patent system into a first-to-file system, thus aligning it with Europe and many other industrialized nations. BIO, the Pharmaceutical Research and Manufacturers of America of Washington, DC, and other industrial groups generally back these patent reform efforts, saying they will streamline patent reviews and will help to reduce costly litigation over patents and patent applications. However, critics of the new legislation argue that some of these provisions will weaken the hand of inventors at universities and startup companies. For example, Carl E. Gulbrandsen, who is managing director of the Wisconsin Alumni Research Foundation in Madison, Wisconsin, asserts that the reforms, if implemented, would "decrease the value of patents, make it more difficult to license and increase the cost of enforcement, which impacts innovators disproportionately more than large companies." He also questions whether the new law is compatible with the US Constitution. "Times are hard enough as it is to start a company," he says. "The last thing investors want is uncertainty, which is exactly what will happen if this proposed legislation becomes law." *Jeffrey L Fox*

Drugmakers use real-world patient data to calibrate product development

On June 22, Paris-based Sanofi announced a partnership with pharmacy benefits manager Medco Health Solutions, of Wilmington, Delaware, to feed real-world evidence into its early-stage product development efforts. The companies did not disclose financial terms, but the agreement entitles the French drug maker to use data from Medco's wholly owned subsidiary, United BioSource Corporation (UBC), to determine patient populations who are in need of new treatments, identify patients suited to particular drugs, compare new drugs to current treatments and ensure treatments are used in the most effective way. Another recent collaboration to integrate real-world treatment information into product development came on 2 February, when London-based AstraZeneca unveiled an alliance with HealthCore, the health outcomes research arm of Indianapolis-based health insurer WellPoint. Other large pharma firms are lining up similar initiatives, says Rich Gliklich, CEO of Outcome Sciences, a Cambridge, Massachusetts–based outcomes research consultancy—a sign that the drug industry is moving to a world in which randomized clinical trials will still be necessary but no longer sufficient to ensure the commercial viability of its products.

Several large biotech companies contacted by *Nature Biotechnology* were unwilling to comment on the topic, even though it is relevant to many of the industry's major biologics franchises. These are complex drug markets with multiple products and multiple sub-populations, and thus amenable to comparative effectiveness research. By incorporating 'real world' analyses, biopharma companies could potentially examine the effectiveness of marketed drugs, pinpoint the specific settings in which a particular drug works best and identify the most promising opportunities for new drug development. Even so, this information, if applied to comparative effectiveness research, could prove to be a double-edged sword. "It could actually increase revenue if your drug comes out on the winning side of the research. By the same token you could also lose out," says Brett Gaspers, managing director of Objective Insights, an Edmonds, Washington–based healthcare business analysis consultancy.

Prompted by rising drug prices, payers have started flexing their muscles and conducting their own independent analyses. As a consequence, drug firms are likely to be pushed into this area if they do not jump. "It's not something that's avoidable," says Tehseen Salimi, vice president for global evidence and value development at Sanofi. UK pharma company AstraZeneca takes a similar view. "We think the greater risk is for us to be not aware of the outcomes and the safety that our products deliver," says Brian Sweet, AstraZeneca's executive director, development. "I think if we don't do this, we're not delivering what the market is requesting."

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As healthcare systems around the world cope with burgeoning populations of aging patients, health resources are being stretched and companies are increasingly having to consider reimbursement in decision making.