NEWS & ANALYSIS

Major patent reform moves closer

Stakeholders and lawmakers continue to negotiate about the most significant changes in US patent law in over 50 years.

Bethan Hughes

The Patent Reform Act 2007, which passed from the House on 18 July and the Senate on 20 July, proposes "possibly the biggest changes that we have seen since 1952," says Hans Sauer, Associate General Counsel for Intellectual Property at the Biotechnology Industry Organization (BIO).

The impetus for reform has come, in particular, from high-tech and software companies who are regularly involved in patent litigation. Cynthia Lopez Beverage, a patent litigator at Morrison and Foerster explains: "these companies want to reduce the strength of patents because it seems that their industry has spawned entities notoriously named patent trolls (for definition, see Supplementary information S1 (box). One high-tech or software patent may cover technology that is part of a multi-component product. As a result, patent trolls have more frequent opportunities to send threats [to companies] demanding that they cease and desist from infringing their patents."

By contrast, biotech and pharmaceutical companies, who have a small number of patents per product, want strong patent validity protection and enforceability because they rely heavily on the strength of their patent portfolios for investment. "The current bills contain provisions that would weaken the protection afforded to patent holders, which include many innovative US business sectors," says Ken Johnson, Senior Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA).

The concern about weakening patent protection stems from the proposed introduction of 'post-grant review proceedings', a system that would allow patents to be challenged at the US Patent and Trademark Office (USPTO). "The only way that a patent can currently be challenged is by litigation in court, which is costly and often time-consuming," explains Professor Arti Rai, Duke University Faculty of Law, USA, "so the idea is to have a low-cost administrative proceeding as exists in the EU and Japanese patent offices."

Two classes are generating the most excitement: drugs that inhibit the enzyme dipeptidyl-peptidase 4 (DPP4) and long-lasting agonists of the glucagon-like peptide 1 (GLP1) receptor. DPP4 inhibitors block the enzyme that degrades GLP1, which is released when food is consumed to stimulate the pancreas to produce and secrete insulin. Nissen, for one, says that he is encouraged by the attention being paid to cardiovascular risk in DPP4 inhibitors. Currently, Januvia (sitagliptin; Merck) is pending approval in the US and has received a positive opinion in the EU, and BMS expects to file for approval of saxagliptin in the first half of 2008.

Like many newer drugs, however, there is some evidence that Januvia is not more effective than older drugs such as the...
sulphonylureas, and some experts say further investigation is needed to determine its side effects (NEJM 356, 437; 2007; Ann. Intern. Med. 16 July 2007; epub ahead of print). Goland says that is a concern for all DIEWS | NATURE complete removal of the provision. reports, BIO and PhRMA want either requirement for applicants to provide search applicants and examiners.” With the new invention and the prior art. Fear of the safest thing is to make as few examination quality because people are conducting negatively impacts patent practice of citing negatively. The challenge with these agents is getting them to persist long enough without being degraded to be effective. So far, Byetta (exenatide; Amylin/Eli Lilly), an injectable GLP1-receptor agonist derived from Gila monster lizard saliva, has been a hit: worldwide sales totalled US$152.1 million in the second quarter of 2007, up 54% from the same period last year. The next GLP1 analogue expected to launch is liraglutide (NovoNordisk), which has been designed to resist degradation.

Another novel class highlighted at the American Diabetes Association meeting in June is inhibitors of the sodium glucose transporter. BMS — one of the companies racing to be first to market with a drug in this class — announced that no adverse events were reported in its 14-day, 47-participant Phase II study of dapagliflozin, which promotes the excretion of excess glucose into the urine. In the next 25 years, pharmacogenetics might also help shepherd drugs through the approval process. In April, the Diabetes Genetics Initiative, a partnership involving Lund University, Sweden, and the Broad Institute of Harvard and MIT and the Novartis Institute for BioMedical Research (NIBR), Massachusetts, USA, announced the discovery of three regions of human DNA that contain genetic risk factors for type 2 diabetes. Several more have since been highlighted in other genome-wide scanning studies (Nature Rev. Drug Discov. 6, 590–591; 2007).

Such efforts could provide insights into the underlying causes of diabetes and help develop better biomarkers, particularly early in the disease stage, says Tom Hughes, head of diabetes research at NIBR. “It will perhaps help us to understand how different patients manifest the disease, and allow us to begin asking whether different treatments work well or less well depending on their genetic makeup,” he says. “I think that’s something over time you’re going to see more and more studies addressing.”

challenged, under the new proposals this challenge would happen in the USPTO under a lower standard of evidence than would be required in court,” Sauer says. “The new system, without appropriate safeguards, provides opportunities for gamesmanship and we think it will force cheap licenses for the patented technology that the company being challenged would concede rather than risk losing their patent.”

Post-grant review proceedings at the USPTO would also increase the workload of the resource-limited agency. To address this, on 19 July the Judiciary Committee approved an amendment that would ensure that the USPTO receives the patent application fees which were previously diverted. Also, in a bid to help the patent examiners improve patent quality, applicants will be required to submit search reports on how the prior art has been researched. BIO and PhRMA are concerned about this requirement, owing to the common practice of citing inequitable conduct during patent litigation.

“Currently,” says Sauer, “inequitable conduct negatively impacts patent examination quality because people are scared of being too helpful — unfortunately the safest thing is to make as few representations as possible about the invention and the prior art. Fear of inequitable conduct litigation chills communication between the patent applicants and examiners.” With the new requirement for applicants to provide search reports, BIO and PhRMA want either meaningful inequitable conduct reform or complete removal of the provision.

Another contentious amendment, popular with high-tech and software companies that have multi-component products, is the way that damages awards are calculated when a patent is infringed. Presently, a patent owner who wins a patent infringement case is entitled to damages, which must at least amount to a reasonable royalty. The new proposal provides a standard for calculating a reasonable royalty that requires the court to consider “the economic value attributable to the invention’s specific contribution over the prior art,” which is widely believed would result in reductions in awards that benefit the infringer, not the patent holder.

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Sauer also believes that these changes will affect the way that commercial licensing deals are negotiated: “universities may ‘front load’ their licence agreements, asking for more money upfront, which goes against the interests of companies who need their money for drug development, not to in-license technologies.” There is also a fear that these damages provisions will lead to disruption of the market if existing licence agreements are breached because it is less expensive to infringe a patent than to pay the agreed royalties.

One proposal that is widely welcomed is the switch from first to invent to first to file. This change would bring the US system in line with the rest of the world, in a step towards international patent law harmonization. “Biotech companies need to think about prosecution and enforcement of their patents throughout the world,” says Dr Gladys Monroy, a partner at Morrison and Foerster and former co-chair of the Intellectual Property Group and Life Sciences Group, “increased harmonization results in greater consistency, which, in turn, results in greater investment.”

Although not opposed to first to file, Dr Patrick Jones, President of the Association of University Technology Managers (AUTM), states that the reform “has to take into consideration the uniqueness of the US system, which has supported the creation of small and agile technology businesses.” The AUTM wants to ensure that first to file preserves the current provisional system and provides a grace period to encourage the early publication of research without precluding subsequent filing of a patent application.

Despite the general ‘want’ for first to file, it is not clear whether it will pass this year as stakeholder negotiations are currently focused on the damages provisions and the post-grant review proceedings. Both BIO and PhRMA are working closely with other stakeholders and lawmakers to try to improve the bills. Johnson concludes: “we are trying to find a way to accommodate the concerns of other stakeholders without doing damage to the patent system and innovation. We have made a lot of progress but we are not there yet.”