IP FLASH

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America Invents Act:
For US IP, the cheese has been moved

Implementation of the America Invents Act (AIA) has catalyzed a paradigm shift in how companies seek to obtain and leverage intellectual property (IP) in the United States. In particular, the post-grant review proceedings created by the AIA have proven to be powerful weapons for invalidating patents – game changers for both patent owners and patent challengers alike. The proceedings typically cost less than one-tenth that of district court litigation, require a lower burden of proof, and are completed within one year. As of the middle of May, the new proceedings had resulted in the cancellation of most or all of the challenged claims in over 75% of the final decisions.

The US has also switched to a "first inventor to file" patent regime and expanded the scope of the "prior art". The first inventor to file patent system places a premium on speed and efficiency in preparing and filing applications as early and as completely as possible. The collective impact of the first-to-file regime, expanded prior art and new review proceedings is to increase the importance of conducting preliminary patentability searches, and in carefully crafting and executing strategies that take into account these changes in the US.

The success of the new post-grant proceedings in invalidating patents is shining the spotlight on the importance of patent quality over patent quantity. In response, companies are adopting value-added strategic approaches in which inventors, IP counsel and executives work closely to create and implement tailored strategies for assessing patentability, preparing and prosecuting patent applications, enforcing/leveraging IP rights and challenging the patents of others. Companies are retaining experienced IP counsel adept at navigating the interplay between patent prosecution and the evolving nuances of the new proceedings. Companies are also shifting focus and resources from district court litigation to the new patent office proceedings.

If it continues unabated, the current success rate of the new proceedings will have a negative impact on the biotech industry, which heavily relies on patent rights as crucial not only to attracting funding, but also to partnering and protecting discoveries. That said, the proceedings are here to stay, and need to be considered in strategies for protecting, securing, defending, and/or challenging IP rights in the US. Additionally, these strategies need to be regularly reassessed, since they appear likely to change and evolve significantly over the next several years as emerging case law and precedent establish and clarify the procedures and nuances of these newly-established proceedings.

EMA

Tracking effects

London/Brussels – Public awareness of reporting on medication side effects is rising. The European Medicines Agency (EMA) said in May that this might be the explanation for the highest numbers of adverse drug effects measured ever. With an increase of 26% compared to 2012, the Agency last year counted over a million potentially drug-related side effects in its EudraVigilance database – a web-based data system that collects, manages and analyses reports of suspected side effects of medicines. At the beginning of May, the EMA and national drug regulators passed on their first report to the European Commission under the new Pharmacovigilance Regulation.

New regulation supports ADR reporting

According to the document, adverse drug reaction (ADR) reporting has increased sharply since implementation of the new legislation, with over 9,000 more patient reports received and approximately 175,000 more Individual Case Safety Reports (ICSRs). Of even more interest, 47% of the 100 signals confirmed by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) led to label changes during the data-lock period (2 July 2012–1 July 2013), 9.3% of the signals led to referral procedures, and as of August 2013, 119 medicines had made the EMA list for additional monitoring. While documentation of ADRs has become more comprehensive, measures for recognising potential harm early on – like risk management plans – are now routine for all new centrally authorised product applications, the Agency said. Furthermore, the implemenation of Periodic Safety Update Reports has apparently supported the timely minimisation of risk. Since the Regulation came into force in July 2012, 135 post-authorisation safety studies (PASS) have been published on the EU PAS (Post-Authorisation Studies) register, said the Agency.