IP FLASH

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Patent Prosecution in the Era of IPR

INTER PARTES REVIEW *(IPR) is a new post-grant cancellation proceeding that has had a dramatic impact on the US patent system. This hybrid proceeding of patent reexamination, court trial, and appellate procedure has been gaining popularity since its inception, with 1,800 IPRs filed since September 2012. Most IPRs have been filed in the electronic arts, but approximately 14% of IPRs are in biotech/pharma, and those numbers are increasing.*

IPRs owe their popularity to their relatively inexpensive nature, short timelines compared to district court challenge (just one year from institution to final decision in comparison to a multi-year court litigation), and bias towards the patent challenger – with about 75% of all challenged claims being canceled. The bias toward challengers results in part from a lower standard to prove invalidity compared to the courts – a "preponderance of the evidence standard" versus "clear and convincing evidence". Since there is also no presumption of validity, the US Patent Trial and Appeal Board (PTAB) readily reconsiders prior art considered by the examiner. The standard for claim construction is also more favorable to the challenger, because the PTAB construes claims using the broadest reasonable interpretation (BRI) in light of the patent specification. This standard also increases the chances of a finding of invalidity.

Unevenness in the playing field means that patentees must have a focus on future IPRs when prosecuting patent applications. A proactive approach can help prepare and/or mitigate IPR attacks. This kind of proactive approach can include one or more of the following strategies: (1) for important applications, filing several applications under expedited examination to deter potential challengers from filing additional IPR petitions; (2) drafting dependent claims that contain limitations claimed in a variety of ways to secure slightly different scope; (3) introducing claims narrowly tailored to important embodiments; (4) including a glossary of terms in a specification to avoid application of an overly-broad BRI standard; (5) if available, including evidence of non-obviousness supported by expert declarations, to have a developed record that can be relied upon by patentees in early stages of IPR.

While patent owners are at a clear disadvantage in an IPR, early and thorough preparation should maximize the chances of having claims that cover important embodiments emerge unscathed. ■

Orphan quake

MARKET STUDY Biopharma companies and patient organisations often link "unmet medical need" to orphan drug development. Of course that's true, but a new market report published at the end of October by Evaluate Ltd (London) suggests you can also make a lot of money in the area. The market experts predict the current US$ 69.5bn global orphan drug market will reach sales of US$ 176bn in 2020. Patient populations are by definition small (up to 200,000 patients in the US, 255,000 in the EU), but orphan drugs represent big per-patient outlays. By 2014, the average orphan drug cost per patient and year was five times higher than for an average non-orphan medicine. According to Evaluate, Phase III development cost is half that of non-orphans, development time is similar, and anticipated return on investment is 1.89 times greater. The research experts predict three European companies will be on the heels of orphan-drug frontrunner BMS (projected sales 2020: US$ 11.1bn): Novartis at #2 with US$ 10.5bn, Celgene at #3 with US$ 10.4bn, and Roche at #4 with US$ 9.9bn. ■

ANTHONY RAESIDE
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? How will orphan drugs affect the biotech market in the future?

! *Orphan drugs are no longer a niche segment of the market, and are projected to account for 19% of the prescription drug market by 2020. Insurers will be looking carefully at tools to arrest cost growth.*

Pictures: upper left: SKGF; right: Evaluate Ltd