Healthy resistance

Medical device patents are largely immune to patent reform, argues Cooley's **Orion Armon** and **Angela Campbell**

In the decade since the Supreme Court of the US (SCOTUS) held in *eBay Inc v MercExchange, LLC,* that patent owners are not entitled to a presumption favouring injunctive relief, changes in patent law have generally weakened patent rights. But medical device patents have hardly been affected. Compared to all other patents, medical device patents have a higher overall litigation win rate, higher damages awards for infringement, a higher permanent injunction win rate and are less likely to be invalidated in *inter partes* review (IPR).

District court litigation win rates

From 1995 to 2014, the average overall win rate at summary judgment or trial for patent owners in district court cases was 33%, but medical device patent owners' overall win rate was 40% – the highest win rate reported, and shared only with biotech and pharma patent owners.[1]

Medical device patents are also associated with higher median damages awards. The median damages award for patents from 1995 to 2014 was $5.4m while for medical device patents, the median award was $19.4m.

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Furthermore, we calculated that median adjudicated royalty rates for infringement of medical device patents between 2009 and 2014 was 13.8%, or about 8% higher than the 5% median royalty rate[2] for all patents.

Finally, in cases involving medical device patents decided between 2008 and 2014 in which lost profits were awarded, we calculated the average award was over $55m and the median award was over $67m.

Injunction success rate

Medical device patent owners win permanent injunctive relief more often than other patent owners. Reviewing contested motions decided between 2009 and 2014, we found that the post-trial win rate for permanent injunctions involving medical device patents was 75%, or 10 percentage points higher than the 65% win rate for all other patent owners.

Section 101 challenges under *Alice*

The number of patents invalidated under 35 USC § 101 for lack of patent-eligible subject matter dramatically increased after SCOTUS decided *Alice Cor Pty Ltd v CLS Bank Int'l* in 2014. Patents on computer-implemented inventions are especially vulnerable under *Alice*. In contrast, medical device patents are largely unaffected by USC § 101 challenges. Since 19 June 2014, only two patents related to medical technologies were invalidated for

Figure 1

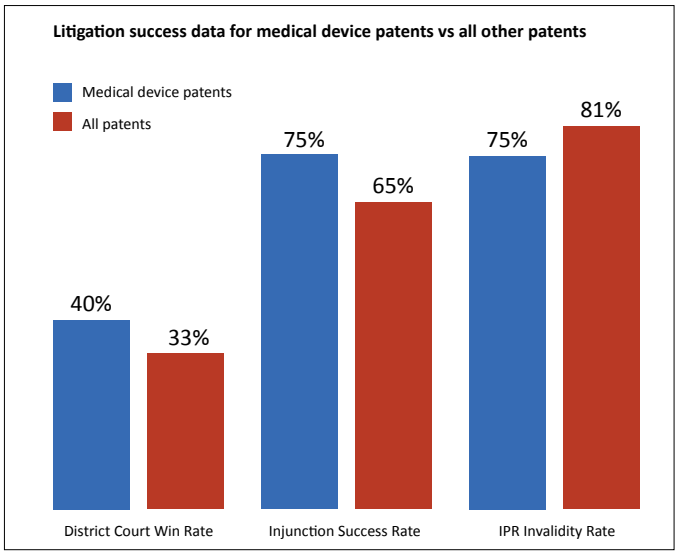
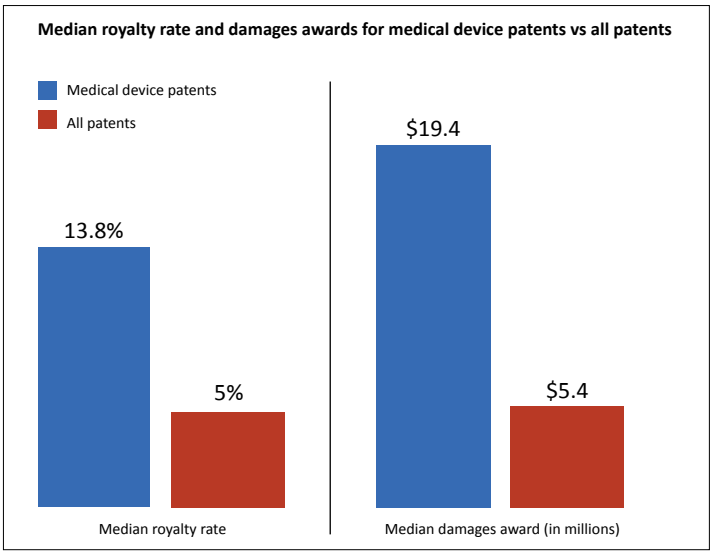


Figure 2



failing to claim patent-eligible subject matter[3] and they were directed to computerised diet analysis and to testing vehicle operators for impairment.[4] We were unable to find any cases in which patents covering actual medical devices have been rendered invalid since *Alice* was decided.

Withstanding IPR validity challenges

Medical device patents also better withstand IPR invalidity challenges than other patents. Our statistics indicate that, in cases that reach a final written decision by the Patent Trial and Appeal Board (PTAB), the average invalidity rate for petitioned claims is 81%. For medical device patents, the average invalidity rate for petitioned claims is 6 percentage points lower, or 75%. When the IPR institution rate is taken into account (ie, the percentage of cases that the PTAB allows to proceed past the petition stage to a full IPR trial) the overall invalidity rate for medical device patent claims in IPR falls to about 56%. This invalidity rate is 10 to 15 percentage points higher than the historic invalidity win rate in district court litigation, but plainly the IPR process is not catastrophic for most medical device patent owners.

Analysis

Medical device patents are withstanding the tides of patent reform better than most. But medical device companies can do more to protect and strengthen the value of their patents as patent reform continues.

First, write patent applications for the PTAB. Comprehensively describe the state of the art in patent applications to reduce the risk that the PTAB - or a jury - will fall prey to hindsight bias when reviewing the validity of your patents. Rapid technological advancement can make even significant inventions seem obvious five or 10 years later.

Secondly, allocate more resources to researching the prior art before filing patent applications. Truly understanding the state of the art and the contents of the prior art makes it easier to decide whether a new invention is truly new and non-obvious, and enables the patent prosecutor to draft a better patent disclosure and claims. Accused infringers will find the best prior art to support their invalidity defences, so you may as well grapple with it during the application process, when you will have the ability to modify claims to overcome the art and the perspective to decide whether it is worthwhile to even pursue a patent application.

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Thirdly, prioritise patent applications that cover commercially valuable technology. If you cannot articulate how you make money from an invention, it is probably not worth patenting.

If you follow these steps, your patents should continue to withstand developments in the law and remain a valuable asset.

Footnotes

1. See PricewaterhouseCoopers' *2015 Patent Litigation Study: A change in patentee fortunes* available at http://www.pwc.com/en_US/us/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf
2. KPMG, *Profitability and Royalty Rates Across Industries*, available at http://www.kpmg.com/Global/en/IssuesAndInsights/ArticlesPublications/Documents/gvi-profitability-v6.pdf (data includes litigation and non-litigation royalty rates, suggesting that litigation royalties were above 5%).
3. *DietGoal Innovations LLC v Bravo Media LLC*, No. 13-Civ-8391 (SDNY 8 July, 2014) (similar invalidating orders were issued by the Eastern District of Texas and the Western District of Oklahoma) and *Vehicle Intelligence and Safety LLC v Mercedes-Benz USA, LLC,* No. 13-CV-4417 (N.D. Ill. 29 Jan 2015).
4. See *DietGoal Innovations*, US Patent No 6,585,516 (method and system for computerised visual behavior analysis, training, and planning) and *Vehicle Intelligence and Safety,* US Patent No 7,394,392 (expert system safety screening of equipment operators).

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