

## Using A 'Commercial Success' Declaration In IPR

*Law360, New York (March 21, 2016, 11:02 AM ET) --*

The Patent Trial and Appeal Board conducts trials, including inter partes, post-grant, and covered business method patent reviews and derivation proceedings, hears appeals from adverse examiner decisions in patent applications and re-examination proceedings, and renders decisions in interferences.

According to the latest U.S. Patent and Trademark Office statistics the cumulative number of America Invents Act petitions filed from Sept. 16, 2012, until Jan. 31, 2016, is 4,475 in the following breakdown: IPRs (4,049; 91 percent), CBMs (411; 9 percent), and PGRs (15; 0 percent). In fiscal year 2015, 1,737 IPR petitions were filed and in fiscal year 2016 through the end of January, 471 have already been filed. Petitions are concentrated by technology. Three technological areas represent 93 percent of the petitions this fiscal year: electrical/computer (TCs 2100, 2400, 2600, 2800) represents approximately 50 percent; mechanical/business method (TCs 3600, 3700) approximately 29 percent; and bio/pharma (TC 1600) approximately 14 percent.

Parties have the opportunity to submit declarations from different types of experts to support the various legal and technical arguments and positions that they are taking in front of the PTAB.

One option that appears to be seldom used is retaining a financial expert to submit an affidavit on commercial success, something that is often used in district court litigation when patent invalidity, specifically obviousness, is an issue. A commercial success analysis may enhance certain cases and fact patterns. The following are some examples where a commercial success declaration may assist a party with the issue of obviousness:

- Where only a subset of independent claims or patents are being challenged: In instances where the product at issue is covered by a number of patents or independent claims and only a limited number are being addressed, a comparison of financial data either as part of a before and after approach or based on assumptions provided by a technical expert may demonstrate that the commercial success of the product can or cannot be effectively linked to the patents or claims at issue.
- Where there is a track record for the product that predates the patent or patents at issue: Strong economic data demonstrating sales, growth,



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profitability and market share that predates the patent application date or approval date of the patent or claims at issue may present a problem for the party attempting to prove that the commercial success is related to the later patents and not the earlier ones. Large or increased promotional activity at or around the approval of the later patents may also make it more difficult to demonstrate a nexus that links the commercial success of the product to the patents at issue.

- Where there are robust economic data on the product which is being replaced by the product that is covered by the patent or patents at issue: In situations where the product covered by the patents at issue is replacing a product that has already demonstrated strong economic data on sales, growth, profitability and market share there are unique concerns. A comparison of the economic data between the new product that is covered and the older product that is not covered, may not clearly illustrate incremental advantages of the new product over the old. A situation where there is strong economic data for the new product but little incremental advantage over the older product not covered by the patents at issue can leave one with a potentially ambiguous or contentious conclusion related to either the commercial success of the new product or the nexus needed to link the commercial success to the patents at issue.

A commercial success declaration or report typically examines some or all of the following types of financial and economic data, with the case specific fact patterns and data availability being primary constraints to the ultimate analysis:

- Sales — units and dollars, typically this includes both absolute levels and growth rates.
- Profitability — gross margin, operating profit and net profits are profit margins that are often analyzed. The analysis usually examines absolute levels and trends. In certain instances a break even analysis can be performed, assuming the appropriate research and development and pre-launch data is available on a company or industry basis.
- Market share — absolute shares and trends over time.
- Market size — absolute amounts and trends over time.
- Comparison of financial data to competing products, products that the patented product is replacing, and/or relevant industry data.
- Comparison of projections and planned performance to actual market performance where there were company estimates prior to launch.
- In certain situations additional industry specific analyses may prove useful. For example in pharma and biotech, comparing the desired indications that the company initially sought to the actual indications granted by the U.S. Food and

Drug Administration may provide additional insight as to the commercial success of the product.

- Review of other drivers of financial performance unrelated to the patent or patents at issue such as promotional activity, marketing and branding. Comparing these levels and trends to industry trends or historical company levels may be useful in forming a conclusion. Being able to isolate the promotional activity to the products covered by the patents at issue can be a challenge, particularly when the product is one of a number for the company or the division, and the detail of the promotional spend is not captured at the product level.

There does not appear to be a consensus in the case law or among economic experts as to a specific value or threshold amount for economic data such as sales, profitability, and market share that is necessary or required in order to conclude that the product at issue is commercially successful. Sometimes the financial expert is required to look at certain data in the context of other data in order to render an opinion. For example, small market share in a very large and profitable growing market may have a different relevance to a high market share in a shrinking and declining small market. In instances where all the economic data point in the same direction, a conclusion is often easier to reach compared to an instance when the data are not consistent or are insufficient to perform all the analyses that the financial expert may desire to perform. In all instances, the analysis and ultimate conclusions are data driven and fact specific. The experience and judgment of the financial expert, along with an understanding of the legal framework, and coordination with the technical team to fully understand the issue of nexus, is typically needed to form an opinion on commercial success.

Petitions before the PTAB typically do not have the same budgets or discovery as district court litigation. The cost and availability of the data typically used in a commercial success analysis along with the expense of retaining another expert appear to be the two main obstacles. A preliminary search and analysis of available data, including a preliminary discussion with other experts particularly on the issue of nexus, can be done very easily in cases that, on their face, have promising fact patterns — it is always quick to reach the answer that the data does not exist.

Assuming that sufficient data do exist to perform an analysis, the cost of a commercial success declaration need not be a budget issue. In district court litigation it is often the deposition and trial along with the preparation that represents the majority of the time and expense in a commercial success budget — the cost of the initial report is a fraction of that, and more importantly easy to predict once you know what data are available.

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