799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

vizient®

June 26, 2020

Submitted via email to: PTABNPRM2020@uspto.gov

Mail Stop Patent Board
Director of the United States Patent and Trademark Office
Attn: Michael Tierney, Vice Chief Administrative Patent Judge
P.O. Box 1450
Alexandria, VA 22313-1450

Re: PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence (PTO-P-2019-0024)

Dear Vice Chief Administrative Patent Judge Tierney,

Vizient, Inc. appreciates the opportunity to comment on the United States Patent and Trademark Office (USPTO) proposed rule, "PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence" (PTO-P-2019-0024).

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates the efforts of various government entities, including USPTO, to develop and implement regulatory frameworks that support competitive marketplaces, particularly for pharmaceutical products. Vizient is committed to minimizing and mitigating rising health care and drug costs to preserve access to care. Both biosimilars and generic drugs represent important avenues for cost mitigation within the pharmaceutical supply chain.

As USPTO is aware, several provisions of the Leahy-Smith America Invents Act ("AIA"), such as those related inter partes review (IPR) and post-grant review (PGR), are important tools to improve the patent system and help correct patent abuses. In addition, recent research evaluating the use of IPR to challenge pharmaceutical patents concluded, "the IPR process can meaningfully contribute to ensuring that invalid patents do not block timely availability of generic drugs."[1] Vizient appreciates the current structure of AIA proceedings, particularly the presumption in favor of the petitioner for a genuine issue of material fact created by testimonial evidence submitted with a patent owner's preliminary responses, when deciding to institute certain reviews.

In the Proposed Rule, USPTO proposes to eliminate this presumption and indicates the Board will consider the evidence to determine whether a petitioner has met the applicable standard for institution of the proceeding. To support this change, USPTO notes concerns, including that the presumption in favor of the petitioner may be viewed as discouraging patent owners from filing testimonial evidence with their preliminary responses. Vizient is concerned USPTO's proposed change to the presumption disrupts current practices that have helped foster competition. For example, current practices have been helpful in stopping invalid patents from blocking access to generic drugs and biosimilars. In addition, the Proposed Rule does not make clear how testimonial evidence would be evaluated, or whether patent owners currently do not provide testimonial evidence in their preliminary response solely because of the presumption being in the petitioner's favor. As such, Vizient encourages USPTO to carefully reconsider these proposed changes as they create additional, unanswered questions regarding future processes and may have far-reaching implications for much needed pharmaceutical competition.

Conclusion

Vizient welcomes USPTO's discussion of the proposed regulatory changes related to the AIA, which provides an opportunity for stakeholders to inform USPTO on how specific proposals will impact the drug supply chain and, ultimately, our members. Vizient looks forward to working with USPTO and the administration to support competition in the U.S. marketplace.

Vizient's membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic

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[1] Darrow, J.J., Beall, R. & Kesselheim, A.S. (2019). The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents. *Appl Health Econ Policy,* 17(1):47-54, doi: 10.1007/s40258-018-0420-8.

medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank USPTO for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
Vice President of Public Policy and Government Relations
Vizient, Inc.