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VIA ELECTRONIC DELIVERY: PTABNPR2018@uspto.gov

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Mail Stop Patent Board
Director of the United States Patent and Trademark Office
P.O. Box 1450, Alexandria, VA 22313-1450

Attn: *Vice Chief Administrative Patent Judges Michael Tierney or Jacqueline Wright Bonilla*
PTAB Notice of Proposed Rulemaking

Re: **Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before
the Patent Trial and Appeal Board; Docket No: PTO-P-2018-0036**

Dear Under Secretary Iancu:

Thank you for the opportunity to comment on the USPTO's proposed changes to the claim construction standard for interpreting issued claims in trial proceedings before the Patent and Trial Appeal Board (PTAB). As a global biopharmaceutical company dedicated to the discovery and development of truly innovative and life-changing medicines for patients, Celgene depends heavily on consistent and predictable scope and duration of granted patent rights. Thus, we applaud the agency's efforts at furthering such consistency by proposing harmonization of the claim construction standard of PTAB post-grant patent adjudication proceedings with that applied in federal district courts and the ITC and by providing for consideration by the PTAB of prior claim construction determinations in civil actions or cases before the ITC.

Proposal to Change Claim Construction Standard in PTAB Trials

By aligning the practices of the PTAB with that of other adjudicatory courts, the USPTO is better fulfilling Congress' intent in creating the new post-grant adjudication mechanisms for patents, i.e., *inter partes* review (IPR), post-grant review (PGR) and covered business method patents (CBM) proceedings. Congress replaced the examinational *inter partes* reexamination with the adjudicatory *inter partes*

review, and created PGR as a mechanism for the early (and fast) adjudication of the validity of newly-issued patents, providing means for a third party to gain clarity with respect to freedom to operate.

Patent examination is a negotiation between the patent examiner and patent applicant. In the examination process the examiner employs a broadest reasonable interpretation (BRI) standard for claim construction in an effort to come to a mutual understanding with the applicant as to the meaning of the claims and to reduce the risk that an issued claim will be interpreted more broadly than is justified. Once issued, the claims of a patent are, by statute, presumed valid and are interpreted based on the ordinary and customary meaning of the terms used, as refined or defined by the specification and prosecution history (i.e., intrinsic evidence), with extrinsic evidence generally determining meaning only when ambiguity remains.

Given that IPRs, PGRs and CBMs are adjudicatory proceedings to determine patent claim validity, it is most logical and fair for the PTAB to employ the same claim construction in these proceedings as courts apply in similar patent validity determinations. Likewise, because the ability to amend/substitute claims in IPRs, PGRs and CBMs is severely limited, both in scope and process, and that the PTAB is expected to adjudicate, rather than examine, such new claims, it is reasonable to employ the same claim construction standard for claim amendments/substitutions as is used in the underlying IPR, PGR or CBM action.

Thus, Celgene fully supports the USPTO's proposed rule change which would result in claim terms being given their ordinary and customary meaning, as defined and refined by the specification and prosecution history, with extrinsic evidence used judiciously and with ambiguities being resolved to preserve patent validity.

Proposal to Give Consideration to Prior Claim Construction Determinations

As with the proposed change in the claim construction standard, requiring the PTAB to give consideration to the construction of a claim term determined by a federal district court or the International Trade Commission (ITC), in a prior civil action or proceeding, should result in greater consistency in patent term interpretations and validity determinations. With consistent claim term interpretation comes greater predictability, for both patent owners and patent challengers, of patent claim validity, which may incentivize early resolution of disputes and may increase judicial efficiency and reduce costs by, for example, reducing the frequency of multiple challenges in multiple adjudicatory venues. Should the PTAB elect to give deference to prior claim constructions, the efficiencies and cost reductions would likely be even more tangible.

Thus, Celgene also fully supports this aspect of the USPTO's proposed rule change and would encourage the PTAB, in practice, to give a high degree of consideration, if not full deference, to the prior claim term constructions of federal district courts and/or the ITC when timely provided in an IPR, PGR or CBM proceeding.

Conclusion

As a leader among the world's largest companies in percentage of revenues reinvested in research and development,¹ Celgene has demonstrated its commitment to making the significant investments of

¹ The 2017 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD. Available at <https://www.kowi.de/Portaldata/2/Resources/fp/2017-EU-Industrial-RD-Investment-Scoreboard.pdf>.

money and time required to create more and better innovative medications for patients suffering from some of the most serious and life-threatening diseases. In 2017, we reinvested 45.5% of our revenue into research, discovery and development of such therapies.² Patent rights are essential to sustaining such investments and uncertainty in either the scope or duration of such rights disincentives and increases the risk of loss of return on those investments, resulting in less money being available to bring the therapies of tomorrow to fruition.

The USPTO's proposed rule changes will create greater consistency in the adjudication of validity of issued patent claims; increase judicial and economic efficiencies and better implement Congress' intent with respect to IPR, PGR and CBM proceedings. As such, Celgene supports rapid finalization of the regulation and recommends the new rules be applied to claim constructions by the PTAB in IPRs, PGRs and CBMs after the effective date of the regulation.

Thank you for your consideration of our comments.

Sincerely,



Peter A. Cicala
Corporate Vice President, Intellectual Property
and Chief Patent Counsel

² Celgene 2017 Annual Report. Available at: [http://files.shareholder.com/downloads/AMDA-262QUJ/6204845187x0x978672/138C3639-1839-499D-8191-34F9E08A0CBD/Celgene AR complete PDF 041718.pdf](http://files.shareholder.com/downloads/AMDA-262QUJ/6204845187x0x978672/138C3639-1839-499D-8191-34F9E08A0CBD/Celgene%20AR%20complete%20PDF%20041718.pdf).