From: Salsberg, Corey
Sent: Friday, November 11, 2016 7:38 AM
To: After Final Practice <afterfinalpractice@USPTO.GOV>
Subject: Novartis Comments on Post-Prosecution Pilot Program (P3) (Fed. Reg. Vol. 81, No. 132; p. 44845-49)

Dear Mr. Tamayo or Whom it May Concern,

Attached for the Office's consideration, please find Novartis' comments regarding the "Post-Prosecution Pilot Program (P3)."

Should you have any questions, please do not hesitate to contact me.

Corey Salsberg
Vice President, Global Head IP Affairs
701 Pennsylvania Ave. N.W., Suite 725
Washington, DC 20004 USA

Phone +1 (202)-662-4369
Fax: +1 (202) 628-4764
Mobile +1 (202) 604-8433
corey.salsberg@novartis.com
www.novartis.com

Corey Salsberg
Vice President, Global Head
IP Affairs

Novartis Services Inc.
701 Pennsylvania Ave. N.W.,
Suite 725
Washington, DC 20004 USA
T: +1 (202)-662-4369
F: +1 (202) 628-4764
corey.salsberg@novartis.com

November 11, 2016

VIA E-MAIL ONLY
AfterFinalPractice@uspto.gov

Novartis Comments on Post-Prosecution Pilot Program (P3) **(Fed. Reg. Vol. 81, No. 132; p. 44845-49, July 11, 2016)**

Novartis is a global healthcare company whose mission is to discover new ways to extend and improve patients' lives. We invent and develop our medicines through a science-based approach to pharmaceutical R&D, largely fueled by the incentives of the patent system. As we have said in comments to other quality initiatives, the quality of the system and of the patents that emerge from it are of utmost importance, not just to us as a frequent user, but to the patients whose lives are ultimately impacted by the strength, consistency and reliability of the system that enables the development of their treatments and cures. With that context, we continue to be pleased with the Office's efforts to improve patent quality, and with its continuous engagement with its stakeholders throughout the Enhanced Patent Quality Initiative (EPQI), including this opportunity to provide feedback on the Post-Prosecution Pilot Program (P3 Program).

As a general matter, we welcome the introduction of the P3 Program pilot, which we view as a promising new procedure that could play an important role in the Office's broader efforts to improve patent quality and reduce application backlogs. With that in mind, we offer the following suggestions that we believe could make the program stronger, and lead to its widespread use and acceptance by Examiners and Applicants alike.

Extension of the P3 Filing Deadline and Conference Window: First, we recommend that the Office extend the deadline to file a P3 Request from two months to three months from the date of the Final Office Action. This additional time would enable Applicants to more thoroughly consider and weigh the various after-Final options now available under the program, and to better prepare a P3 Request which includes a requisite Response and optional claim amendments, affidavit or other evidence, as set forth in 37 C.F.R. §1.116. In turn, the Office would likely benefit from higher quality submissions. We also suggest that the Office expand the window in which to hold the P3 conference from 10 days to 15 days in order to provide more flexibility in scheduling that is to occur between the SPE and the Applicant.

Use of Slides in the P3 Conference: We also suggest that the Office formalize what we understand to be its current practice of permitting Applicants to submit and use presentation slides during the P3 conference. Based on similar interactions in other contexts, we believe that visual presentations would be an effective way to communicate and facilitate dialogue between an Applicant and the Examiner panel during such conferences. We therefore suggest that all Applicants be given the opportunity to submit presentation slides, and that these slides be made of record in the proceedings. These slides, however, should not be counted as part of the 5-page P3 Response, as their primary role would be to facilitate the conference.

Expanded P3 Conference Presentation Times: We further recommend that the Office expand the time for conference presentations from 20 minutes to 30 minutes, allowing 20 minutes for the Applicant's presentation and an additional 10 minutes for the Examiner panel to ask questions and present its perspective on the issues. A presentation by the Examiner panel providing its perspective on each issue would be valuable to the process, as the Examiner will likely have formed such views at that time based on its prior review of the Applicant's written submissions. Adding this feature to P3 conferences will enable Applicants to directly and efficiently address any factual or legal issues raised by the panel at the time of the conference, ultimately supporting the Program goal of improving patent quality.

Additional Guidance on Procedural Implications of P3 Program Participation: We further request that the Office provide clarification and additional guidance on the procedural implications of participating in the P3 Program. Several important procedural implications of P3 participation are currently unclear, including (1) what weight, if any, the PTAB will give to a prior adverse decision by an Examiner panel; and (2) whether the Applicant will be permitted to rely on arguments and evidence submitted with a P3 Request or during a P3 conference in a subsequently-filed Appeal Brief. Clarity on these and similar issues will help to encourage more Applicants to use the P3 Program.

Enabling Measures and Ongoing Assessments: To enable and optimize program efficacy and impact, we also recommend that the Office continue to assess and evaluate ways to increase Examiners' use of the P3 Program through such mechanisms as internal incentives, allowance of sufficient Examiner time to use the process, etc. Likewise, the Office should consider taking measures to ensure that an Applicant who submits a P3 Request in proper form and scope will be able to predictably and consistently participate in the P3 Program (to the extent openings in the Pilot are available). Last, to continue to enable and optimize program impact, we encourage the Office to monitor usage, provide publicly accessible data on the Program, and commit to a set time frame to reassess whether the Program is meeting its goals.

We thank the Office for its continued engagement with stakeholders throughout the EPQI, and for this opportunity to provide feedback on the P3 pilot. We look

forward to continued engagement on the program and on other quality-related initiatives.

Respectfully submitted,
/s/ Corey Salsberg

Corey Salsberg*
Vice President, Global Head IP Affairs

* David Carpenter, Leslie Fischer, Brannon Latimer, Laura Madden, and Matthew Mulkeen of Novartis participated in the drafting of these Comments.