From: Rosato, Michael

To: <u>Trials</u>

Cc: Parmelee, Steve; Gerrard, Sonja; Schonewald, Stephanie L.; Medina, Rolando

 Subject:
 IPR2019-00636, -00637

 Date:
 Monday, July 1, 2019 5:31:01 PM

 Attachments:
 IPR2019-00636 - POPR, Page 14.pdf

IPR2019-00637 - POPR, Pages 15-16.pdf

## Trials.

Patent Owner (Guardant Health) respectfully requests Board authorization to correct an inadvertent error presented in the patent owner preliminary response (POPR) in IPR2019-00636 filed May 28, 2019. Specifically, to the extent the POPR (page 14) suggests that the challenged '992 patent is entitled priority to an application filed September 4, 2012--that is incorrect.

The same error was carried over in the second IPR on the '992 patent – IPR2019-00637. As such, we would also like to similarly correct the POPR (pages 15-16) filed June 10, 2019 in this case. Accordingly, Patent Owner requests authorization to file a corrected POPR deleting the three sentences as shown by strike-through text in the attached marked up documents for each of the respective cases. The corrected POPRs would only delete the identified content—no new content will be added. Once the corrected POPRs are filed, the original POPRs can be expunged from the record.

Parties have conferred and Petitioner has indicated they oppose this request. If a conference call is deemed necessary, parties will provide times of mutual availability. Respectfully,

## **Michael T Rosato**

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## (i) Schmitt's disclosure of detecting a "single base substitution" is not prior art

The '992 patent claims priority to several previously filed applications, the earliest of which was filed <u>September 4, 2012</u>. EX1001, front page. The petition does not dispute the priority claim of the '992 patent.

The Schmitt patent was filed as Application No. 14/386,800 on September 20, 2014 and issued as U.S. Patent No. 9,752,188 on September 5, 2017—both of which are <u>after</u> the September 4, 2012 earliest priory date of the '822 patent. The Petition alleges the Schmitt patent is prior art because it "claims the benefit of U.S. Provisional Application 61/613,413 filed on March 20, 2012 (EX1012) ("'413 Provisional")." Pet. 20.

But the petition materials fail to show that the material in the Schmitt patent that is relied upon in the petition was disclosed in and carried through from the '413 Provisional. See, e.g., Cox Communications, Inc. v. AT&T Intellectual Property I, L.P., IPR2015-01227, Paper 70 at 40 ("[T]he material relied upon as teaching the subject matter of the challenged claims must be carried through from that earlier filed application to the reference patent being used against the claim.") (citing In re Giacomini, 612 F.3d 1380, 1383 (Fed. Cir. 2010)); see also Ariosa Diagnostics, Inc. v. Illumina, Inc., IPR2014-01093, Paper 69 at 11 (same).

Here, the petition includes only a single conclusory statement that "the teachings that Petitioner relies upon were carried forward from the '413



B. Petitioner fails to establish that Schmitt discloses detecting "two or more different members selected from the group of members consisting of a single base substitution, a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion"

Petitioner alleges that "Schmitt *explicitly* teaches DCS can detect 'single base substitution' and 'CNV." Pet. 52 (emphasis added). No such "explicit" teaching can be found in Schmitt.

First, the disclosure that Petitioner relies on for "single base substitution" is not present in Schmitt's priority document and therefore Schmitt does not qualify as prior art to the challenged patent in this regard. Second, Schmitt does not "explicitly" disclose detection of copy number variation as asserted—Schmitt does not describe doing so anywhere in the reference. Finally, as to the recited insertion/deletion or gene fusion recited in claim 1, Petitioner tacitly concedes that Schmitt does not disclose detection of "an insertion or deletion (indel), or a gene fusion." Instead, Petitioner argues that Schmitt "can detect" other mutations—but this argument is both factually and legally deficient.

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Here, the petition includes only a single conclusory statement that "the teachings that Petitioner relies upon were carried forward from the '413 Provisional to Schmitt." Pet. 20. But this conclusory assertion is unsubstantiated and incorrect.

For instance, Petitioner critically relies on disclosure within Example 4 of the Schmitt patent as teaching "single base substitutions" of the challenged claims.

