

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORESIGHT DIAGNOSTICS INC.,
Petitioner,

v.

PERSONALIS, INC.,
Patent Owner.

IPR2024-00170
U.S. Patent No. 11,584,968

**PETITIONER'S AUTHORIZED REPLY
TO PATENT OWNER'S PRELIMINARY RESPONSE**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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Patent Owner asserts that it “disputes whether Chan discloses WGS [whole genome sequencing]” in related IPR2023-00224. POPR 12. This is contradicted by its expert’s admission in that proceeding that Chan is a “whole genome sequencing reference.” EX1127.72 (Furneaux Decl. in IPR2023-00224) (citing Newman 7)) (“Newman referenced several whole genome sequencing references as follows: ... ‘Previously published methods employing amplicon^{8,10,11}, whole exome¹², or *whole genome*^{9,32,33,24} **sequencing** would not be sensitive enough to detect ctDNA in most patients with NSCLC....”). Newman’s citation 32, bolded by Dr. Furneaux as a WGS reference, is the Chan reference that Patent Owner now alleges does not disclose WGS. EX1044.12. Patent Owner was correct when its expert flagged Chan as a WGS reference before it changed positions in this proceeding.

Patent Owner’s related position that institution should be denied under 37 C.F.R. § 42.104(b)(3)-(4) for supposed failure to construe “whole genome sequencing” also has no merit. First, the petition sets forth numerous grounds of invalidity, and Patent Owner does not dispute in its POPR that Ley (Ground 3) and Okosun-II (Grounds 4 and 5) disclose WGS. Indeed, Patent Owner’s expert has admitted that Ley discloses “performing whole genome sequencing two times (once on the patient’s normal genome, and again on the tumor genome).” EX1127.110.

Also, at this stage, it is apparent at a minimum that the petition establishes a reasonable likelihood that at least one of the challenged claims is invalid because the references disclose WGS under the term's plain meaning (the petition's primary position) as well as alternative constructions. The Federal Circuit addressed such a circumstance where a patent owner argued that a petitioner "should have presented argument and evidence under [a particular] construction in the petition." *Axionics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1383 n.10 (Fed. Cir. 2023). The court explained that there is "no support for a rule that would create challenges including line-drawing and unworkability problems and consistency with the regulation that governs the content of a petition, which does not direct a petitioner to raise, address, and apply alternative possible constructions, but instead requires a petitioner affirmatively to state '[h]ow the challenged claim is to be construed.' 37 C.F.R. § 42.104(b)(3)." *Id.*

Given Patent Owner's prior admission that Chan discloses WGS, Petitioner could not have reasonably anticipated that Patent Owner would take the opposite position in its POPR here. Nevertheless, the petition explains that Chan discloses WGS on DNA from tumor tissues as well as leukocyte DNA from the buffy coat fraction. Petition 29 (citing Ex. 1008.211, 218); Ex1001 54:63 ("the buffy coat contains leukocytes"). The petition also cites the portion of Dr. Quackenbush's declaration where he testifies that applying the Board's

preliminary construction of WGS from IPR2023-00224 leads to the same result as follows:

If [the preliminary] construction [of WGS] is applied, Chan's MPS of the tumor and buffy coat samples satisfies the definition. First, Chan's approach is "non-targeted" because the sequencing libraries are prepared from randomly sheared genomic DNA, and thus reads are intended to be generated from all DNA in a sample, as opposed to targeted sequencing of chosen or selected DNA loci (e.g., the exome only). Second, Chan's approach sequences all or almost all of the genome, specifically noting "haploid genome coverage" of 29.5-fold (tumor DNA) and 43-fold (buffy coat DNA). Thus, on average, each base of the haploid genome was sequenced 29.5 times in the tumor sample, and 43 times in the buffy coat sample, confirming that Chan's nontargeted sequencing approach sequenced all or almost all of the genome.

Ex1100.63 ¶120 (cited at Petition 28).

The Board should therefore reject Patent Owner's proposal to deny institution under 37 C.F.R. § 42.104(b)(3). The petition sets forth all the necessary constructions for the challenged claims in light of the records of the parties' disputes, and also includes for good measure Petitioner's expert's explanation why the prior preliminary construction of WGS would be satisfied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. section 42.6, that on March 19, 2024, a complete copy of the foregoing document **PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE** were served upon the following, by ELECTRONIC MAIL:

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