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Federal Circuit Patent Bulletin: *Bd. of Trs. of Leland Stanford Junior Univ. v. Chinese Univ. of Hong Kong*

June 29, 2017

"[T]he written description requirement [is satisfied] when 'the essence of the original disclosure' conveys the necessary information—'regardless of how it' conveys such information, and even when the disclosure's 'words [a]re open to different interpretation[s].'"

On June 27, 2017, in *Bd. of Trs. of Leland Stanford Junior Univ. v. Chinese Univ. of Hong Kong*, the U.S. Court of Appeals for the Federal Circuit (O'Malley,* Reyna, Chen) vacated and remanded the U.S. Patent and Trademark Office Patent Trial and Appeal Board interference decision involving U.S. patent application Serial No. 13/070,275 (Lo or CUHK) and U.S. Patent No. 8,008,018 (Quake or Stanford), both of which related to testing methods for fetal aneuploidies, conditions in which a fetus either has an abnormally high number of chromosomes (e.g., Down's syndrome, a result of trisomy 21) or an abnormally low number of chromosomes (e.g., Turner's syndrome, a result of a missing copy of an X chromosome), inter alia, that the '018 patent was invalid for inadequate written description. The Federal Circuit stated:

Whether a patent claim satisfies the written description requirement of 35 U.S.C. § 112, paragraph 1, depends on whether the description "clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." [W]hatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed. Substantial evidence

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supports a finding that the specification satisfies the written description requirement when "the essence of the original disclosure" conveys the necessary information—"regardless of how it" conveys such information, and even when the disclosure's "words [a]re open to different interpretation[s]."

The parties dispute whether the Board correctly determined that the '018 patent does not disclose the random massively parallel sequencing of nucleic acid sequences claimed in the later-added claims such that a person of skill in the art would have concluded that the Quake inventors were in possession of the method claimed. First, the parties disagree as to whether the reference to Illumina products in the specification . . . adequately discloses random massively parallel sequencing as the later-added claims require . . . . [T]he Board had to determine what the '018 specification's reference to Illumina products meant at the time of the invention, and whether such a reference encompassed random and/or targeted sequencing. "Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." The parties do not dispute the February 2007 priority date as it appliesto this issue.

The Board concluded that: [G]iven that Dr. Gabriel supports her testimony with published references and given that the language of the Quake '018 patent at 19:48-20:3 does not preclude targeted massively parallel sequencing, we credit Dr. Gabriel's testimony that those of skill in the art could have considered the references in the '018 patent specification to Illumina products to indicate targeted sequencing. The Board relied on Dr. Gabriel's testimony to conclude that the '018 patent lacked sufficient written support. . . . We conclude that the Board erred in its reliance on the portions of Dr. Gabriel's testimony that rely on these references. Both Dr. Gabriel and the Board failed to cite any evidence of targeted or random sequencing on the Illumina platform prior to Quake's filing date. . . . The Board stated that it relied on Dr. Gabriel's testimony, at least in part, because of the "published references" to which she cited. [T]he Illumina references post-date the 2007 priority date, and the other references discuss a platform not referenced in the '018 patent. All of the published references on which the Board relies focus on the Roche 454 platform, not the Illumina platform actually referenced in the specification. The Board did not cite evidence to connect targeted sequencing on the Roche 454 platform to targeted sequencing on the Illumina system, nor has the Board explained what it found persuasive about the Roche 454 platform references.

Indeed, Stanford offers evidence to show that the Illumina sequencing platform—a second-generation MPS platform first released in 2006—came after the Roche 454 platform—a first generation MPS platform first released in 2005. And the systems operate differently: although the Roche 454 system could apply targeting techniques using its low-throughput PCR amplification reactions, the Illumina platform could generate far more data using its high-throughput system but had difficulties applying simple PCR amplification procedures due to its scale. Yet the Board never compared the difficulty of performing targeted or random sequencing on an Illumina platform. We further note that Dr. Gabriel and the Board failed to cite to the Roche 454 references with specificity, leaving us with no reviewable record to conclude that the disclosed methods or platform would have been applicable to Illumina on Quake's priority date.

Dr. Gabriel did testify that those of ordinary skill in the art, both in 2006–07 and today, would consider the Roche 454 platform to be an MPS platform; Stanford does not dispute this point. But both Dr. Gabriel's testimony and the Board's discussion on this issue fail to explain why the Board could properly rely on

testimony focused on the Roche 454 platform for any purpose beyond its discussion of MPS platforms in general, when the '018 patent specifically cites to the Illumina platform. Nor has Dr. Gabriel or the Board explained why we should use conclusions about the Roche 454 platform to conclude that Illumina teaches only targeted sequencing.

Second, the Board found that a person of skill in the art "would have understood the discussion of massively parallel sequencing [in the '018 patent] to refer to sequencing targeted, predetermined portions of the DNA in a sample, not sequencing of random DNA." . . . The Board's finding that the '018 specification's language does not preclude targeted MPS ignores the fact that the same description might be able to disclose both random and targeted sequencing. Put another way, even if the '018 specification could indicate targeted sequencing, it could also disclose random sequencing, or it could disclose both random and targeted sequencing. The Board frames its finding in terms of an erroneous premise: the Board's task was to determine whether the '018 patent's written description discloses random MPS sequencing, as recited by the later-added claims, not whether the description does not preclude targeted MPS sequencing. The Board's error on this issue is compounded by its failure to explain the meaning of key sentences and phrases in the specification's discussion of the sequencing process, and its failure to compare these statements to the claim limitations.