

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARIOSA DIAGNOSTICS,
Petitioner,

v.

ISIS INNOVATION LIMITED,
Patent Owner.

Case IPR2012-00022¹
Patent 6,258,540

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Request for Rehearing
37 C.F.R. § 42.71

I. SUMMARY

Isis Innovation Limited (“Patent Owner”), requests rehearing of the Final Decision (“Dec.”), dated September 2, 2014 (Paper 166). Paper 168. Ariosa Diagnostics (“Petitioner”), also requests rehearing of the Final

¹ This Case has been joined with IPR2013-00250.

Decision. Paper 167. In the Final Decision, we determined that claims 1, 2, 4, 5, 8, 19, 20, 24, and 25 were unpatentable under 35 U.S.C. § 102(b), but that claims 3, 12, 13, 15, 18, 21, and 22 were not shown to be unpatentable. *See* Dec. 56. We determined further that the joinder statute allows joinder of issues by the same party, as well as joinder of parties. *Id.* at 22.

Patent Owner requests rehearing on a single issue. Specifically, Patent Owner argues that we must reconsider our determination that the joinder statute allows joinder of issues by the same party, as well as joinder of parties, in view of the expanded panel decision in *Target Corp. v. Destination Maternity Corp.*, IPR2014-00508, slip. op. 7, 11 (PTAB Sept. 25, 2014) (Paper 18).

Petitioner requests rehearing of our determination that the combination of Simpson (Ex. 1025) and Kazakov (Ex. 1014) does not render unpatentable claims 1, 2, 4, 5, 19–22, 24, and 25 under 35 U.S.C. § 103(a). In particular, Petitioner contends that determination “was erroneously premised on the factual finding that the combined method of *Kazakov*. . . and *Simpson* . . . was limited to quantitative testing for chromosomal abnormalities, *e.g.*, aneuploidy,” whereas the combination of those references would have rendered obvious a method of testing for fetal gender. Paper 167, 1.

II. DISCUSSION

A party challenging a Final Written Decision by way of request for rehearing must identify specifically all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d). The challenging party bears the burden of showing that the decision should be modified.

A. PATENT OWNER’S REQUEST FOR REHEARING

We have carefully considered Patent Owner’s Request for Rehearing based on the panel decision in *Target Corp. v. Destination Maternity Corp.*, IPR2014-00508, slip. op. 7, 11 (PTAB Sept. 25, 2014) (Paper 18), but do not find it persuasive. First, that decision is not a precedential decision, and thus is not binding. Second, an expanded panel of the Board granted rehearing of that decision, and agreed with our determination that the joinder statute allows joinder of issues by the same party, as well joinder of parties. *See* IPR2014-00508 (PTAB Feb. 12, 2015) (Paper 28).

We, therefore, *deny* Patent Owner’s Request for Rehearing.

B. PETITIONER’S REQUEST FOR REHEARING

Petitioner contends that, as set forth in the Petition filed in IPR2013-00250 (Paper 1, “the ’250 Petition”), “it would have been obvious to use the Y chromosome fetal sequence specific primers of *Simpson* or *Bianchi* to amplify fetal DNA of paternal origin in a male fetus for the purpose of identifying the sex of a male fetus.” Paper 167, 2. Petitioner points also to the claim chart as to claim 5 in the Petition filed in IPR2012-00022 (Paper 1, “the ’022 Petition”), which notes that Simpson taught the use of PCR to amplify Y sequences, and the experiments conducted by Kazakov would have resulted in the amplification of Y-specific sequences that were contained in Y-specific sequences. Paper 167, 2. (citing Ex. 1007 (“Mansfield Declaration”), ¶¶ 51–69, 74)). According to Petitioner, such methods are qualitative rather than quantitative. *Id.*

Petitioner contends further that our determination was premised on the finding that “in the combined method the objective was solely to test for

fetal aneuploidy.” Paper 167, 6–7 (citing Dec. 43–45). That erroneous fact finding, Petitioner asserts, led to the conclusion that Petitioner failed to demonstrate that the combination of Simpson and Kazakov rendered the claimed method obvious by a preponderance of the evidence. *Id.* at 7–8 (citing Dec. 46). That is, Petitioner argues, the rarity of fetal DNA in maternal serum would not have been an issue as PCR is able to detect the equivalent of a single male cell. *Id.* at 9.

Petitioner’s contentions do not persuade us that we overlooked or misapprehended any evidence or argument in the Final Decision. The claim chart as to claim 5 filed in the ’022 Petition states:

Simpson teaches that PCR was used to amplify Y sequences from fetal cells in women to confirm the sex of a male fetus (*Mansfield Decl.* ¶74).

Additionally, the experiments conducted by Kazakov would have resulted in the amplification of Alu repeats that contained Y-specific sequences, as demonstrated in the *in silico* genomic data provided in the Kazakov declaration as well as the scientific data provided in the Mansfield declaration (*Mansfield Decl.* ¶¶51-69).

’022 Petition, 51. The ’022 Petition provides no further analysis as to that claim. In particular, we note that the claim chart does not state that such methods would have been qualitative, rather than quantitative. Paragraphs 51–69 of the Mansfield Declaration were cited to demonstrate that the primers used in the Kazakov reference would have resulted in amplification of sequences from the Y chromosome. Paragraph 74 cites the Simpson reference for its teaching of primers specific for the Y chromosome. Thus, those portions of the Mansfield Declaration also do not state that such methods would have been qualitative rather than quantitative.

Moreover, the issue of whether detecting fetal Y chromosomal sequences is qualitative rather than quantitative is irrelevant to our Decision, as we determined that the preponderance of the evidence did not support that the combination of Simpson and Kazakov provided a reasonable expectation of success that the fetal DNA would have been present in maternal serum in sufficient quantities for detection using amplification methods such as PCR. Dec. 43. In particular, as noted in the Final Decision, Petitioner relied on Simpson for its teaching that fetal cells, or at least fetal DNA, are present in maternal blood. Dec. 39 (citing '022 Petition, 49). Kazakov was relied upon for its teaching that the level of extracellular DNA increases in the blood of pregnant females. *Id.* (citing '022 Petition, 50). We noted that although Simpson suggested that DNA would be found in levels sufficient to be determined using amplification reactions, such as PCR, by teaching that Y chromosome specific signals were seen in women carrying a male fetus, we determined that a preponderance of the evidence supported the finding that the source of that DNA was fetal cells, and not cell-free DNA. *Id.* at 40. Thus, we considered specifically Simpson's teaching of using PCR to detect Y-chromosome specific signals.

In concluding that Petitioner had not established that the combination of Simpson and Kazakov rendered obvious challenged claims 1, 2, 4, 5, 19–22, 24, and 25, we noted that the evidence supported that the occurrence of fetal cells in maternal blood was a rare event. *Id.* at 42. The Decision noted also that Kazakov did not consider fetal DNA to be the only source of the increased DNA in maternal serum during the first trimester, but also considered maternal sources, and did not rule out the possibility that the DNA being amplified was only from maternal sources. *Id.* Those findings

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