United States Court of Appeals for the Federal Circuit

ARIOSA DIAGNOSTICS,
Appellant

v.

VERINATA HEALTH, INC.,
Appellee

2015-1215, 2015-1226

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2013-00276, IPR2013-00277.

Decided: November 16, 2015

MARK A. LEMLEY, Durie Tangri LLP, San Francisco, CA, argued for appellant. Also represented by DARALYN JEANNINE DURIE, ALEXANDRA HELEN MOSS; GREG GARDELLA, Oblon, Spivak, McClelland, Maier & Neustadt, LLP, Alexandria VA.

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Before PROST, *Chief Judge,* WALLACH, and TARANTO, *Circuit Judges.*

TARANTO, *Circuit Judge.*

Verinata Health, Inc. owns U.S. Patent No. 8,318,430, which describes and claims methods of noninvasive prenatal testing for the presence of fetal chromosomal abnormalities. In particular, the methods may identify "aneuploidy," *i.e.*, the presence of an abnormal number of copies of a chromosome—say, three rather than the normal two for chromosome 21, an abnormality that characterizes Down Syndrome. The methods involve obtaining blood samples from several pregnant women; isolating from the samples genomic DNA molecules not contained in cells; choosing particular DNA sequences—some on a chromosome of concern, some not; indexing by maternal source the chromosomes or regions containing those sequences; amplifying (making many copies of) the group of chromosomes or regions; performing massively parallel sequencing on the resulting pool; using the indexing to count, for a particular maternal source, the number of sequences from chromosomes of concern versus the number from reference chromosomes or regions; and determining based on the comparison whether there are fetal chromosomal abnormalities, such as an extra copy of a chromosome of concern.

Ariosa Diagnostics, Inc. petitioned the Patent Trial and Appeal Board for inter partes review of claims 1–18 and, in a separate petition, claims 19–30, challenging the claims for obviousness under 35 U.S.C. § 103. The Board concluded that Ariosa had not met its burden of proving that claims 1–18 and 19–30 would have been obvious. *Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-276, 2014 WL 5454541 (PTAB Oct. 23, 2014); *Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-277, 2014 WL 5454542 (PTAB Oct. 23, 2014). We vacate the decisions and remand for further consideration because of one

matter that the Board's language suggests it did not sufficiently consider.[1]

BACKGROUND

Verinata and Ariosa are competitors in the relatively new field of noninvasive prenatal diagnostics, which includes testing for fetal chromosomal abnormalities. For many years, prenatal chromosomal testing required invasive, high-risk procedures, such as amniocentesis. Noninvasive tests, based on the combination of ultrasound observation and measurement of biochemical markers in blood samples drawn from the pregnant woman, suffered from low accuracy—in a matter where accuracy is very important. The 1997 discovery of cell-free fetal DNA circulating in maternal blood suggested the possibility of superior noninvasive tests, but turning the possibility into a reality presented significant challenges.

One challenge involved the proportion of the total amount of cell-free DNA in maternal blood that came from the fetus. That proportion is typically less than 10 percent. Some scientists seeking to use the 1997 discovery focused on distinguishing fetal DNA from maternal DNA in a blood sample. By separating fetal from maternal DNA, or determining the particular fetal/maternal ratio of cell-free DNA, certain counting methods could try to discern which fetus-specific chromosomes had an abnormal number of copies.

Verinata's '430 patent, with a priority date of January 2010, does not rely on separating fetal from maternal cell-free DNA or, even, determining the fetal/maternal ratio of cell-free DNA. '430 patent, col. 5, lines 63–65. Rather,

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[1] The Board's decisions are the same in all respects material to this opinion. Instead of providing duplicative citations, we cite only the decision in IPR2013-276, which we call simply "*Ariosa*."

the '430 patent describes a counting technique applied to an overall pool of DNA segments, selected for comparing a chromosome of concern (say, chromosome 21) with a reference chromosome (or chromosomal region), making the comparison by identifying the respective DNA sequences. Fetal aneuploidy (in the case of, for example, three versus two copies of a chromosome) may be determined by comparing the number of sequences generated from the chromosome of concern with the number of sequences generated from a reference chromosome—counting copies from all cell-free DNA, whether fetal or maternal. *Id.*, col. 13, lines 59–64. But because cell-free fetal DNA is such a small proportion of total cell-free DNA, the elevation in the target-sequence count will be small in an overall sample; and for the numerical elevation to be significant and sufficiently reliable for prenatal testing, a large sample must be created and sequenced. The '430 patent describes doing so by amplifying the target and reference sequences, pooling samples from several women and indexing them for later identification, and using massively parallel sequencing. '430 patent, col. 1, lines 41–48; *id.*, col. 6, lines 20–27; *id.*, col. 12, lines 56–63.

Claim 1 of the patent states:

> 1. A method for determining a presence or absence of a fetal aneuploidy in a fetus for each of a plurality of maternal blood samples obtained from a plurality of different pregnant women, said maternal blood samples comprising fetal and maternal cell-free genomic DNA, said method comprising:
>
> (a) obtaining a fetal and maternal cell-free genomic DNA sample from each of the plurality of maternal blood samples;
>
> (b) selectively enriching a plurality of non-random polynucleotide sequences of each fetal and maternal cell-free genomic DNA sample

of (a) to generate a library derived from each fetal and maternal cell-free genomic DNA sample of enriched and indexed fetal and maternal non-random polynucleotide sequences, wherein each library of enriched and indexed fetal and maternal non-random polynucleotide sequences includes an indexing nucleotide sequence which identifies a maternal blood sample of the plurality of maternal blood samples,

wherein said plurality of non-random polynucleotide sequences comprises at least 100 different non-random polynucleotide sequences selected from a first chromosome tested for being aneuploid and at least 100 different non-random polynucleotide sequences selected from a reference chromosome, wherein the first chromosome tested for being aneuploid and the reference chromosome are different, and wherein each of said plurality of non-random polynucleotide sequences is from 10 to 1000 nucleotide bases in length,

(c) pooling the libraries generated in (b) to produce a pool of enriched and indexed fetal and maternal non-random polynucleotide sequences;

(d) performing massively parallel sequencing of the pool of enriched and indexed fetal and maternal non-random polynucleotide sequences of (c) to produce sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences of each of the at least 100 different non-random polynucleotide sequences selected from the first chromosome tested for being aneuploid and sequence reads corresponding to enriched and indexed fetal and maternal

> non-random polynucleotide sequences of each of the at least 100 different non-random polynucleotide sequences selected from the reference chromosome;
>
> (e) based on the indexing nucleotide sequence, for each of the plurality of maternal blood samples, enumerating sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences selected from the first chromosome tested for being aneuploid and sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences selected from the reference chromosome; and
>
> (f) for each of the plurality of maternal blood samples, determining the presence or absence of a fetal aneuploidy comprising using a number of enumerated sequence reads corresponding to the first chromosome and a number of enumerated sequence reads corresponding to the reference chromosome of (e).

'430 patent, col. 63, lines 8–67. Claims 2–18 depend on claim 1 and add various limitations, such as the number of non-random DNA sequences selected, the length of the non-random DNA sequences, and the chromosomes to be tested. *Id.*, col. 64, line 8 through col. 65, line 11. Claim 19, the only other independent claim, differs from claim 1 in that claim 19 requires comparing the tested chromosome region to a chromosome control region, rather than comparing a tested chromosome to a reference chromosome. *Id.*, col. 65, lines 35–36, 55–56, 65, and col. 66, line 7. Claims 20–30 depend on claim 19 and are largely analogous to claims 2–18. *Id.*, col. 66, lines 1–62.

Ariosa petitioned for inter partes review of claims 1–18 and 19–30. It argued that the claimed methods would have been obvious to a relevant skilled artisan in January

2010 in light of three prior-art references: Shoemaker, Dhallan, and Binladen.

U.S. Patent Application No. 2008/0090239, filed in 2008 by Shoemaker et al., discloses a method of determining fetal aneuploidy by isolating fetal cells, not cell-free DNA. A maternal blood sample, known to include a very small number of fetal blood cells, is enriched for blood cells and then dispersed into wells, each well receiving at most one blood cell. Shoemaker ¶¶ 7, 8, 219. A polymerase chain reaction (PCR) technique is used to tag and amplify specific regions of chromosomes in those cells—regions being tested as well as control regions. *Id.* ¶¶ 7, 9. All amplified products are then pooled for sequencing. *Id.* ¶ 121. Non-maternal sequences are identified and used to distinguish wells containing fetal cells from those containing maternal cells. *Id.* ¶ 138. For the wells that contain fetal cells, the ratio of maternal to non-maternal alleles is then compared: certain disparities will indicate the presence of extra copies of fetal chromosomes. *Id.* ¶ 140.

U.S. Patent No. 7,332,277, issued in 2003 to Dhallan, discloses a method of detecting fetal genetic disorders. Dhallan describes using a maternal blood sample to obtain a mixture of cell-free fetal and maternal DNA. '277 patent, col. 31, lines 32–34. Specific DNA sequences are amplified and sequenced. *Id.*, col. 47, lines 38–39. After sequencing, maternal and fetal alleles are distinguished, *id.*, col. 67, lines 28–34, the percentage of fetal DNA in the original sample is calculated, *id.*, col. 67, lines 18–27, and the calculated ratio of fetal to maternal alleles is used to identify chromosomal abnormalities, *id.*, col. 68, lines 56–60.

An article published in 2007 by Jonas Binladen et al. describes a study that involved tagging and sequencing DNA samples from multiple sources simultaneously. The study isolated DNA samples from thirteen species (human, wolf, cheetah, lion, hippopotamus, zebra, mouse,

etc.) using a commercially available extraction kit, then amplified and indexed targeted sequences from those samples by methods of polymerase chain reaction that already were known. The amplified products were then pooled for sequencing, which was performed using a massively parallel sequencing machine.

In its Petitions, Ariosa argued for obviousness based on combinations of Dhallan's teachings about cell-free fetal DNA with Binladen's indexing and sequencing techniques and Shoemaker's method of determining aneuploidy. Specifically, Ariosa argued that "a scientist in this field would have known that Dhallan could be enhanced through use of the PCR amplification techniques utilizing sample indices and massively parallel sequencing of pooled samples as discussed in Binladen." J.A. 208–09. It added "that a skilled artisan would have readily understood that Shoemaker's methods for determining the presence of fetal abnormalities could be carried out with the use of cell-free DNA described in Dhallan and the multiplexed detection techniques taught in Binladen." J.A. 209.

The Board instituted reviews under 35 U.S.C. § 314(a) upon finding a reasonable likelihood that the methods of the '430 patent's claims were unpatentable because they would have been obvious. But after receiving the Patent Owner's Response and accompanying submissions, then Ariosa's Reply and accompanying submissions, and then counsel's oral arguments, the Board upheld all of the claims. The Board concluded that Ariosa did not carry its burden of showing that the claims would have been obvious. 35 U.S.C. § 316(e).

The Board's central point was that Ariosa's Petitions were lacking because "virtually no effort [wa]s made to explain how or where the references differ from the challenged claims, how one of ordinary skill in the art would go about combining their disparate elements, or what modifications one of ordinary skill in the art would neces-

sarily have made in order to combine the disparate elements." *Ariosa*, at *10. The Board discussed all three references—including, repeatedly, Shoemaker. *Id.* at *5, 6, 7, 9, 10, 11. It pointed to concessions of Ariosa's experts, Drs. Morton and Nussbaum, made in depositions after the Institution Decisions, that various modifications would have to be made to combine Dhallan and Binladen, including "that one 'would do a different process to incorporate the tags' . . . and Binladen's 'tagging would not be the way that that was done, because the method of inserting the tag, the way it's done now was not known at that time.'" *Id.* at *9. The Board found unpersuasive Dr. Morton's assertion that "'one of ordinary skill . . . would be able to easily apply the teachings of Binladen to optimize the tags to decrease the error rate and increase the accuracy,'" given that Binladen's tagging method displayed a high error rate and detection of fetal aneuploidy requires "'highly precise methods for quantification.'" *Id.* (citing Dr. Morton's declarations). The Board further noted that Dr. Morton, in her deposition, "was unable to recall describing 'a synthesis of how to put [Shoemaker, Dhallan, and Binladen] together' anywhere in her Declaration." *Id.*

The Board summarized:

> What is lacking in the Petition and accompanying Declarations is an "articulated reason[] with some rational underpinning to support the legal conclusion of obviousness." [*In re*] *Kahn*, 441 F.3d [977, 988 (Fed. Cir. 2006)]. The inadequacy of the obviousness analysis in the Petition and accompanying Declarations is readily apparent when the disparate elements of the references are scrutinized closely, as in Patent Owner's response, and we decline to search through the record and piece together those teachings that might support Petitioner's position. *Cf. DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (Fed. Cir. 1999) ("A brief must make all arguments accessible to the judges, ra-

> ther than ask them to play archeologist with the record.").

Ariosa, at *10.

At the end of its analysis, the Board addressed Ariosa's attempt, through a second declaration of Dr. Morton accompanying its Reply, to bolster the reliance placed in the Petitions on a brochure that describes indexing and massively parallel sequencing using the commercially available Illumina Genome Analyzer System (Exhibit 1010). *Id.* at *10–11. The Board stated:

> This testimony, in effect, replaces the tagging and sequencing techniques of Dhallan and Binladen with the Illumina indexing kit and sequencing platform, but neither Petitioner nor Dr. Morton explains why Exhibit 1010 could not have been presented as part of the asserted ground of unpatentability in the first instance with the Petition.[4] Therefore we accord this aspect of Dr. Morton's testimony no weight.

Id. at *11. In the footnote to that passage, the Board quoted the PTO regulation declaring that "[a] reply may only respond to arguments raised in the corresponding . . . patent owner response," 37 C.F.R. § 42.23(b), and the related explanation that "[r]eply evidence . . . must be responsive and not merely new evidence that could have been presented earlier to support the movant's motion," Rules of Practice for Trials before the Patent Trial and Appeal Board, 77 Fed. Reg. 48,612, 48,620 (Aug. 14, 2014). *Ariosa*, at *11 n.4.

Ariosa appeals the Board's determinations of nonobviousness as to claims 1–18 and 19–30. The appeal is authorized by 35 U.S.C. § 319. This court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

This court reviews the Board's ultimate determinations of obviousness de novo. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013). It reviews for substantial evidence the underlying factual findings, which include findings as to the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, the presence or absence of a motivation to combine or modify with a reasonable expectation of success, and objective indicia of non-obviousness. *See*, *e.g.*, *id.*; *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196–97 (Fed. Cir. 2014); *Tri-Med, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1341 (Fed. Cir. 2010). A petitioner in an inter partes review has the burden of proving a claim's invalidity by a preponderance of the evidence. 35 U.S.C. § 316(e).

A

Ariosa's principal challenge is to the Board's treatment of Exhibit 1010, the Illumina brochure. Pointing to the Board's language about Exhibit 1010, quoted *supra*, Ariosa argues that the Board erred in refusing to consider Exhibit 1010 for what it showed about the background knowledge that a skilled artisan would have possessed, particularly about DNA indexing, in January 2010. We agree with Ariosa up to a point: the Board's language leaves open the distinct possibility that the Board incorrectly limited its consideration of Exhibit 1010.

The Board's language on its face supports Ariosa's interpretation of what the Board meant—that the Board was declining to consider Exhibit 1010, even as evidence of the background understanding of skilled artisans as of January 2010, simply because the brochure had not been identified at the petition stage as one of the pieces of prior art defining a combination for obviousness. If that is what the Board meant, the Board erred. Art can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art

identified as producing obviousness. *Randall*, 733 F.3d at 1362–63. Ariosa's Petitions and opening declarations invoked Exhibit 1010 in that way.

Ariosa included Exhibit 1010 in its Petitions as an exhibit to Dr. Nussbaum's expert declaration. Dr. Nussbaum, in discussing the state of the art of indexing and sequencing technology, stated that "as of 2008, indexed multiplexing was so widespread as a technique that the company Illumina, Inc. offered a commercially available kit for production and analysis of indexed libraries from different samples of origin," and the indexed libraries could have been "analyzed on a commercially-available massively parallel sequencing platform sold by the same vendor." J.A. 876. Ariosa's second expert, Dr. Morton, also named the Illumina sequencing system when discussing the state of the art of massively parallel sequencing, although she did not specifically refer to Exhibit 1010. The Petitions then cited portions of Dr. Nussbaum's and Dr. Morton's declarations for the same proposition—that "[m]assively parallel sequencing methods were in routine use by 2008." J.A. 179. Given those references in the Petitions and supporting declarations, Exhibit 1010 had to be considered by the Board even though it was not one of the three pieces of prior art presented as the basis for obviousness.

That the language of the Board regarding Exhibit 1010 is readily susceptible of being read to rest on an incorrect legal proposition, by itself, does not require setting aside the Board's decisions. We may affirm an agency ruling if we may reasonably discern that it followed a proper path, even if that path is less than perfectly clear. *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285–86 (1974). We also may affirm if an erroneous portion of an agency's ruling is ultimately non-prejudicial, *i.e.*, not material to the bottom-line result given other portions of the agency's ruling. 5 U.S.C. § 706; 28 U.S.C. § 2111; *In re Chapman*, 595 F.3d 1330, 1338 (Fed. Cir. 2010); *In re Watts*, 354 F.3d 1362,

1369 (Fed. Cir. 2004). But we must not ourselves make factual and discretionary determinations that are for the agency to make. *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002); *ICC v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 283 (1987); *SEC v. Chenery Corp.*, 332 U.S. 194, 196–97 (1947).

Here, we cannot confidently discern whether the Board, in its consideration of Exhibit 1010, was actually relying on a legally proper ground rather than the erroneous ground just noted. The Board might have been saying only that the development of the argument invoking Exhibit 1010 in the Petitions was not adequate. This court in *Randall* did not dispense with the need for parties to provide adequately developed explanations when relying on background knowledge based on cited art; the adequacy of the challenger's explanation in that regard was unquestioned in *Randall*. 733 F.3d at 1360. And a PTO regulation provides: "[t]he Board may exclude or give no weight to the evidence where a party has failed to state its relevance." 37 C.F.R. § 42.104(b)(5). In the present case, other than stating that massively parallel sequencing was known by 2008, the Petitions and supporting declarations say little about the relevance of Exhibit 1010, such as how a skilled artisan would have used what it showed about background knowledge in combining or modifying the prior-art references or how it tended to show that a skilled artisan would have had a reasonable expectation of success in achieving the suggested combination and modification.

Giving the inadequate-explanation reading to the Board's statement about Exhibit 1010, though straining the words somewhat, would fit two related aspects of the Board's decisions. First, the Board's statement followed its quotation of Dr. Morton's Reply declaration, which contains little if any more explanation of Exhibit 1010's role than appeared in her original declaration: "[O]ne of ordinary skill in January 2010 would be motivated to index individual samples and pool them for sequencing to

maximize sequencing capacity and to minimize sequencing cost. For example, the Illumina, Inc. product flyer from 2008 states, '[h]arnessing this sequencing power in a multiplexed fashion increases experimental throughput while reducing time and cost.'" *Ariosa*, at *11 (quoting J.A. 1485). Thus, while Dr. Morton's Reply declaration identifies Exhibit 1010 as evincing a motivation to "index individual samples and pool them for sequencing," it does not address whether Exhibit 1010 would have motivated a skilled artisan to replace the quantification methods of Dhallan, *see*, *e.g.*, '277 patent, col. 63, line 55 through col. 65, line 28, with the technique of massively parallel sequencing described by Binladen. Second, at the heart of the Board's analysis in the rest of its decisions is its finding that Ariosa provided inadequate explanation: the Petitions did not "explain how or where the references differ from the challenged claims, how one of ordinary skill in the art would go about combining their disparate elements, or what modifications one of ordinary skill in the art would necessarily have made in order to combine the disparate elements." *Ariosa*, at *10.

Yet the Board did not sufficiently articulate the foregoing grounds for its rejection of Ariosa's reliance on Exhibit 1010 or other grounds independent of the incorrect ground suggested by the Board's language. Perhaps the Board could have done so. But it did not, and we cannot do so for the Board where, as here, the matter is not purely legal.

We likewise are not prepared to find that the error we cannot rule out was non-prejudicial. We will not here draw our own conclusion about whether Exhibit 1010, if considered for what the Petitions (and supporting declarations) adequately presented about it, could have filled the explanatory gap that was the heart of the Board's reason for finding Ariosa's case unproved. Given the complexity of this area, and how seemingly small differences might be significant, we will not undertake to determine whether a proper assessment of Exhibit 1010 should lead to a

reassessment of the explanatory gap. The Board is in a better position to do so. We will therefore vacate the decisions and remand.

We do not direct the Board to take new evidence or, even, to accept new briefing. The Board may control its own proceedings, consistent with its governing statutes, regulations, and practice. 37 C.F.R. § 42.5(a). Those statutes, regulations, and practices embody expedition- and efficiency-based policies that the Board must consider in determining the scope of the remand proceedings.

Congress generally directed that inter partes review proceedings be completed within one year of institution. 35 U.S.C. § 316(a)(11). Reflecting that timing constraint, and the statutory goal of providing a relatively quick and low-cost alternative to litigation over validity, the PTO has established rules that, while necessarily respecting constitutional and statutory guarantees of procedural fairness, are designed generally to require that the parties make their cases in a very small number of filings—with the challenger obliged to make an adequate case in its Petition and the Reply limited to a true rebuttal role. 37 C.F.R. §§ 42.104(b)(5), 42.23(b). Within this structure, even while providing for an estoppel effect on the challenger, 35 U.S.C. § 315(e), Congress assigned to the challenger the burden of persuasion in the dispute, *id.* § 316(e). That burden, together with the procedural rules impartially applied, means that, in some cases, a challenge can fail even if different evidence and arguments might have led to success. We leave to the Board the determination of what remand proceedings are appropriate given the governing policies.

B

Ariosa also challenges the Board's decision on a distinct ground. The Board determined that teachings of Binladen and Dhallan could not be combined because "Binladen's indexing (i.e., tagging) scheme could not be used with Dhallan's restriction-digestible amplification

primers." *Ariosa*, at *10. Ariosa argues that the Board erred in failing to consider some embodiments of Dhallan—those which do not require a restriction-enzyme digestible primer—embodiments that, they argue, could be combined with Binladen. The Board declined to consider those embodiments because the cited "portions of Dhallan were not identified or discussed in the Petition or the accompanying Declarations." *Ariosa*, at *10. In any event, the Board added, Ariosa's explanation was lacking even as to those portions. *Id.*

We see no error in the Board's rejection of Ariosa's reliance, in its Reply submissions, on previously unidentified portions of a prior-art reference to make a meaningfully distinct contention. Ariosa's Petitions quote a portion of Dhallan that states: "Any method that provides information on the sequence of a nucleic acid can be used . . . ." '277 patent, col. 36, lines 6–19; *see* J.A. 189, 215. The supporting declarations state that Dhallan teaches that the sequencing step can be performed using any method. J.A. 360–61 (quoting '277 patent, col. 6, lines 26–34); J.A. 919 (quoting '277 patent, col. 36, lines 6–19). The Petitions and declarations, however, do no more than point to a generic statement in Dhallan that any sequencing method can be used; they make no mention of how the choice of sequencing method influences the use of a restriction-enzyme digestible primer, which occurs in the amplification step. '277 patent, col. 36, lines 6–19. Not until Dr. Morton's Reply declaration did Ariosa identify specific embodiments of Dhallan that do not use restriction-enzyme digestible primers. J.A. 1479 (citing embodiments at '277 patent, col. 11, line 61 through col. 12, line 17; *id.*, col. 12, lines 40–47; *id.*, col. 13, line 66 through col. 14, line 5; *id.*, col. 13, lines 36–42; *id.*, col. 14, lines 15–25).

A governing regulation states that a Petition must identify "[t]he supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge raised, including identifying specific portions of

the evidence that support the challenge." 37 C.F.R. § 42.104(b)(5). Further, "[t]he Board may exclude or give no weight to the evidence where a party has failed to state its relevance or to identify specific portions of the evidence that support the challenge" in the Petition. *Id.* That regulation reflects the combination of efficiency and fairness interests also embodied in the regulation limiting Reply submissions to matter responsive to the Patent Owner's Response. *Id.* § 42.23(b). The Board must make judgments about whether a Petition identified the specific evidence relied on in a Reply and when a Reply contention crosses the line from the responsive to the new. The Board reasonably made those judgments here.

C

Ariosa challenges the adequacy of the Board's consideration of Shoemaker—even though, as we have noted, the Board addressed Shoemaker throughout its analysis. We need not decide, however, whether there are any deficiencies in the Board's consideration of arguments about Shoemaker made and supported in a timely manner by Ariosa. We are remanding the matter regardless. On remand, the Board may decide whether its treatment of Shoemaker should be left as is, supplemented, or revised.

CONCLUSION

For the foregoing reasons, we vacate the Board's finding of nonobviousness and remand.

No costs.

VACATED AND REMANDED