

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC PLC,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case IPR2016-00058
Patent 8,560,034 B1

Before KEN B. BARRETT, BENJAMIN D. M. WOOD, and
GEORGIANNA W. BRADEN, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Medtronic PLC (“Petitioner”) filed a Petition requesting *inter partes* review of U.S. Patent No. 8,560,034 B1 (“the ’034 patent”). Paper 1 (“Pet.”). The Petition challenges the patentability of claim 1 of the ’034 patent on the grounds of anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103. Masimo Corporation (Patent Owner) filed a Preliminary Response to the Petition. Paper 8 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

After considering the information presented in the Petition, we determine that Petitioner has not established a reasonable likelihood that it would prevail with respect to the claim challenged in the Petition. Accordingly, we do not authorize an *inter partes* review to be instituted as to the challenged claim of the ’034 patent.

A. Related Proceedings

One or both parties identify, as matters involving or related to the ’034 patent, Patent Trial and Appeal Board cases IPR2016-00057 (the ’034 patent) and IPR2016-00056 (U.S. Patent No. 7,496,393), and Board of Patent Appeals and Interferences case Interference No. 105,471. Pet. 1; Paper 6, 3; *see, e.g.*, Prelim. Resp. 1.

Additionally, Patent Owner identifies several judicial and administrative matters concerning related patents. *See* Paper 6, 1–4.

B. The '034 Patent

The '034 patent pertains to the processing of measured signals, in the context of blood oxygen saturation systems, in a way “which facilitates minimizing the correlation between the primary signal portion and the secondary signal portion in order to produce a primary and/or secondary signal.” Ex. 1001, col. 1, ll. 15–29. “Complications arising in these measurements are often due to motion of the patient, both external and internal (muscle movement, vessel movement, and probe movement, for example), during the measurement process.” *Id.* at col. 2, ll. 22–26. Motion artifacts, introduced by patient movement, distort the measured signal. *Id.* at col. 3, ll. 5–8.

A monitor for pulse oximetry saturation measurement uses two light emitting diodes (LEDs) that emit light at different wavelengths, for example, red (R) and infrared (IR). *Id.* at col. 4, ll. 46–49, col. 33, ll. 58–65. The light passes through a portion of the body where blood flows, such as a finger, and is received by a photodetector positioned on the opposite side of the finger. *Id.* at col. 4, ll. 49–52, col. 33, ll. 58–62. The '034 patent explains that “[t]he attenuated signals generally comprise both primary . . . and secondary (noise) signal portions.” *Id.* at col. 4, ll. 52–54. The “noise” of the secondary signal includes “venous oxygen saturation and other parameters.” *Id.* at col. 5, ll. 25–26. These other parameters of the secondary portion include “artifacts due to patient movement which causes the venous blood to flow in an unpredictable manner.” *Id.* at col. 4, ll. 31–38, *see also id.* at col. 34, ll. 7–15 (the '034 patent also referring to “[e]rratic motion induced noise”). According to the '034 patent, where the two light signals are measured substantially simultaneously, the secondary signal

components are correlated to each other “because any random or erratic functions affect each measurement in nearly the same fashion” and the primary signal components are correlated to each other. *Id.* at col. 12, ll. 4–10.

In the model of the '034 patent, coefficients relating the two signal portions may be determined by minimizing the correlation between the primary and secondary signal portions. *Id.* at col. 5, ll. 19–29. In the method of claim 1, the two signals (*e.g.*, red and infrared) are mathematically manipulated based on two assumptions. First, the model assumes that the amount of motion affecting each of the two light signals is the same because the two signals are measured so closely together in time. *Id.* at col. 64, ll. 43–44, *see id.* at col. 12, ll. 4–10 (“any random or erratic functions affect each measurement in nearly the same fashion”). Second, the model assumes that the motion components of the two signals are proportional to each other. *Id.* at col. 64, ll. 45–46, *see id.* at col. 12, ll. 5–25 (discussing proportionality constants between the secondary signal portions).

C. The Claim

Claim 1 is reproduced below:

1. A method for measuring saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of two discrete, different wavelengths;

sensing an intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first and second intensity signals including motion components; and

determining said saturation by mathematically manipulating said first and second intensity signals without

subtracting said motion components and with the assumptions that

- i) an amount of motion is the same at the same time for each of said intensity signals, and
- ii) the motion components of said intensity signals are proportional to one another.

Ex. 1001, col. 64, ll. 31–46.

D. Applied References

Reference			Exhibit No.
Prosser	US 5,246,002	Sept. 21, 1993	Ex. 1003
Diab	WO 92/15955	Sept. 17, 1992	Ex. 1004

Petitioner relies also on the Declaration of Dr. Daniel van der Weide, dated October 20, 2015, (Ex. 1002) in support of Petitioner’s arguments.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Reference(s)	Basis	Claim
Prosser	§ 102(a), (b), and (e)	1
Prosser and Diab	§ 103(a)	1

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (2016). Under the broadest reasonable construction standard, claim terms are given their

ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

On this record and for purposes of this Decision, we determine that none of the claim terms requires an express construction to resolve the dispositive issues discussed below.

B. Ground 1: Alleged Anticipation by Prosser

Petitioner asserts that claim 1 is anticipated by Prosser (Ex. 1003). Pet. 21–37. Patent Owner opposes. Prelim. Resp. 43–56.

Prosser pertains to a “noise insensitive pulse transmittance oximeter.” Ex. 1003, Abstr., col. 9, ll. 34–36. Prosser teaches to adjust “the intensity of the LEDs until the differences between the peak and valley values of the red transmittance pulses $[(\Delta R)]$ and infrared transmittance pulses $[(\Delta IR)]$ are substantially equal.” *Id.* at Abstr., col. 8, ll. 47–53. Figure 2 of Prosser is reproduced below:

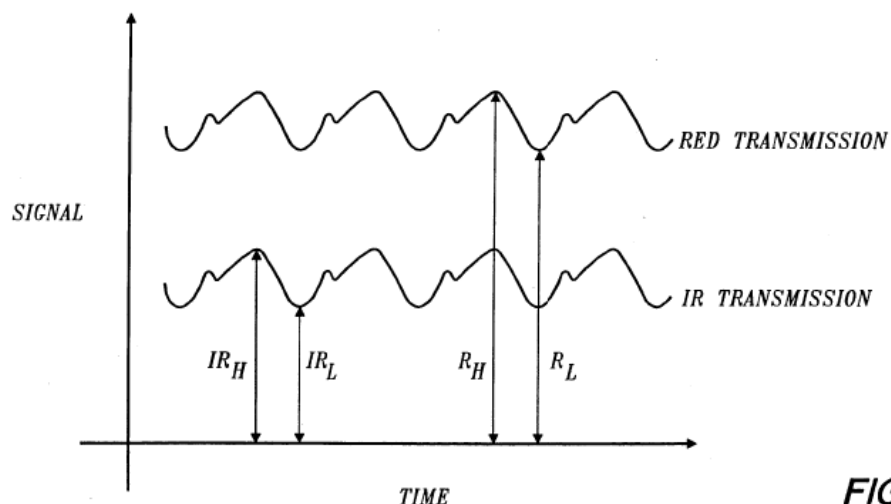


Figure 2 is “a graphical plot as a function of time of the transmittance of light at the red and infrared wavelengths through the finger.” *Id.* at col. 2,

ll. 48–50. Prosser calculates an oxygen saturation ratio in accordance with a known equation, shown below.

$$R_{OS} = \frac{\ln\left(\frac{R_H}{R_L}\right)}{\ln\left(\frac{IR_H}{IR_L}\right)}$$

Id. at col. 1, ll. 36–51, col. 8, ll. 43–45, col. 9, ll. 20–23, Fig. 3 (box 67). Prosser includes a mathematical proof (*id.* at col. 9, l. 36–col. 11, l. 8) which, according to Prosser, proves that “by controlling [the red and infrared LEDs] such that $\Delta R = \Delta IR$, the oxygen saturation ratio calculation is insensitive to noise.” *Id.* at col. 11, ll. 9–13.¹

Petitioner’s argument that Prosser discloses the claimed assumptions is premised on the assertion that “the noise in *Prosser’s* signal model includes motion components.” Pet. 28; Ex. 1002 ¶ 41 (Dr. van der Weide stating the same with the inclusion of the assertion that the conclusion is “clear”); *see also* Pet. 18 (“with Prosser discussing the movement of a patient’s finger as a noise source”); Ex. 1002 ¶ 27 (Dr. van der Weide stating the same). Petitioner has not persuaded us that this assertion is correct.

In support of the assertion, Petitioner points to Prosser’s statement that movement of the patient’s finger is an activity that may trigger the adjustment of LED intensity. Pet. 28 (citing Ex. 1003, col. 6, ll. 64–67); *id.*

¹ Prosser, in the proof, assumes that the respective light transmittance values at systolic pressure are much larger than the corresponding noises at systolic pressure such that the noise is negligible, and Prosser concludes that the oxygen saturation ratio calculation is insensitive to noise. Ex. 1003, col. 10, l. 61–col. 11, l. 13; *compare id.* at col. 10, ll. 45–47 (Equation 10 containing noise components ϵ) *with id.* at col. 11, ll. 5–8 (Equation 12 lacking the noise components after assuming $R \gg \epsilon$).

at 18; *see* Ex. 1002 ¶¶ 27, 41; Ex. 1003, col. 6, ll. 64–67 (the cited portion stating: “For example, movement of the patient’s finger 15 is one common activity that triggers the method of the present invention to adjust the LED intensity levels”). We fail to see, and Petitioner does not explain adequately, how this portion of Prosser—which does not mention explicitly “noise”—ties together the concepts of motion and noise.

Petitioner next states that “*Prosser*’s disclosure is no different from the ’034 patent in this regard, given that the ’034 patent does not separately account for noise caused by motion and noise originating from other sources,” and states that the ’034 patent labels the secondary signal component as “noise.” Pet. 28; *see* Ex. 1002 ¶ 41. We do not find this persuasive because it does not follow necessarily that Prosser is using the term “noise” and accounting for motion and noise exactly as in the ’034 patent.

Prosser, rather than offering a clear indication that Prosser’s “noise” includes motion, distinguishes the two concepts. Prosser explains that “[n]oise may originate from several sources including, but not limited to: preamplifier noise, induced noise from inside the oximeter, induced noise from outside the oximeter, and ambient light noise.” Ex. 1003, col. 1, l. 66–col. 2, l. 2, *see id.* at col. 13, ll. 8–11, 20–24 (describing an alternative embodiment where the pulses are processed using separate circuitry and where “noise” is induced by the use of an electrical cable carrying a repeating square wave to determine the “noise ratio”). Notably absent from the Prosser’s list of “noise” is an explicit reference to motion. Prosser then, in the portion relied upon by Petitioner as mentioned above, discusses patient movement, stating:

[M]ovement of the patient's finger 15 is one common activity that triggers the method of the present invention to adjust the LED intensity levels. During movement of the finger 15, the blood volume and thickness of the finger varies and therefore, the [light transmittance] values of R_H , R_L , IR_H , and IR_L will vary.

Ex. 1003, col. 6, l. 64–col. 7, l. 2; *see also* Ex. 1003, col. 1, ll. 45–51

(explaining that R_H , R_L , IR_H , and IR_L refer to the light transmittance of the red (R) and infrared (IR) wavelengths and at systolic pressure (L) and diastolic pressure (H)). Thus, Prosser is discussing motion in the context of the effect on the light transmittance values of R and IR, values that are used in the oxygen saturation ratio formula, and does not mention explicitly noise in this context. In contrast, Prosser, at a latter part of the specification and in explaining why the disclosed method is insensitive to noise, identifies “noise” as a component separate from and added to the light transmittance values R and IR. *Id.* at col. 10, ll. 16–19 (“To account for noise, we assume that an arbitrary amount of noise is added to R_H , R_L , IR_H , and IR_L , denoted as ϵ_{RH} , ϵ_{RL} , ϵ_{IRH} , and ϵ_{IRL} , respectively”). Accordingly, we are not persuaded by Petitioner's arguments and testimony from its declarant that Prosser's “noise” includes motion components.

Furthermore, even accepting as true Petitioner's argument that “the noise in *Prosser's* signal model includes motion components” (Pet. 28), we are not persuaded that Petitioner has carried its burden. In this regard, Petitioner makes the conclusory argument that, “[b]ecause Prosser measures the signals at substantially the same time and assumes the amount of *noise* is the same for such measurements, Prosser assumes that an amount of *motion* is the same at the same time for each intensity signal (i.e., assumption (i) in claim 1 of the '034 patent).” Pet. 27 (emphasis added, italicizing in original

omitted); *see also* Ex. 1002 ¶ 39 (Dr. van der Weide making the same conclusory assertion). For the second claimed assumption, Petitioner similarly asserts “that the motion components are proportional” because “the noise components (including patent motion) are equivalent.” Pet. 27–28; *see also* Ex. 1002 ¶ 40 (Dr. van der Weide immediately following a recitation of Prosser’s noise component (ϵ) equality equations with the opinion that “the motion components are equivalent”). Petitioner, however, does not explain adequately how the claimed *motion* assumptions are shown by disclosure of *noise* assumptions where motion forms only portion of that total noise.

Petitioner suggests that there might be a situation where the only component in the “noise” is motion. *See* Pet. 28 (“*Prosser* also indicates that, in some instances, the non-motion noise components may be so insignificant that they do not trigger its noise compensation mechanism.”). Petitioner does not direct us to evidence that Prosser discloses, either expressly or inherently, the occurrence of that hypothetical situation where the total noise is composed solely of motion components. *Cf.* Ex. 1002 ¶ 41 (Dr. van der Weide making the same assertion without any supporting citation and without elaboration).

Because Petitioner’s theory of anticipation as to the claimed assumptions pertaining to motion is based on the unpersuasive arguments regarding Prosser’s “noise” (*see, e.g.*, Pet. 36–37), Petitioner has not established a reasonable likelihood that it would prevail in demonstrating anticipation of claim 1 of the ’034 patent.

Lastly, we find persuasive Patent Owner’s argument that Petitioner is relying on an incorrect oxygen saturation ratio equation, which, according to Patent Owner, is an equation used in a mathematical proof not in the actual

determination of the oxygen saturation ratio. Prelim. Resp. 55–56.

Petitioner, in its claim chart, points to, *inter alia*, the following equation for the disclosure of the claimed recitation of “determining said saturation by mathematically manipulating said first and second intensity signals without subtracting said motion components”:

$$R_{OS,NOISE} = \left(\frac{IR_L}{R_L} \right)$$

Pet. 35–36 (citing “Ex. 1003 at 11:5-8; *see also id.* at 9:40-11:13, deriving this equation.”); *see also id.* at 29 (“This final equation is used to determine the oxygen saturation of a patient’s blood” (emphasis omitted)). As mentioned above, Prosser’s method utilizes the following equation to determine oxygen saturation ratio:

$$R_{OS} = \frac{\ln \left(\frac{R_H}{R_L} \right)}{\ln \left(\frac{IR_H}{IR_L} \right)}$$

Id. at col. 8, ll 43–45, col. 9, ll. 20–23, 36–45, Fig. 3 (box 67). We recognize Petitioner also refers to the correct equation, but that is in the context of beginning the mathematical proof. Pet. 25. Nonetheless, even if Petitioner is relying on the disclosure of the proper equation, Petitioner’s reference to two equations without a reconciling explanation creates confusion rather than clarity. Thus, Petitioner has not met its burden.

For the reasons set forth above, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing in its challenge that claim 1 is anticipated by Prosser.

C. Ground 2: Alleged Obviousness over Prosser and Diab

Petitioner argues that claim 1 would have been obvious in light of Prosser (Ex. 1003) and Diab (Ex. 1004). Pet. 37 (section heading).

Petitioner relies on Diab for the disclosure of the claimed assumptions. *Id.* Patent Owner responds by arguing that Petitioner “provides no explanation about how any assumptions specified in *Diab* would apply to *Prosser*’s teachings.” Prelim. Resp. 56. Patent Owner’s argument is persuasive.

Prosser has been discussed above. *See* Section II.B. Diab discloses a pulse oximeter that uses “an adaptive noise canceler that removes erratic motion-induced undesired signal portions in a pulse oximeter.” Ex. 1004, 64–65.² Figure 10 of Diab is reproduced below:

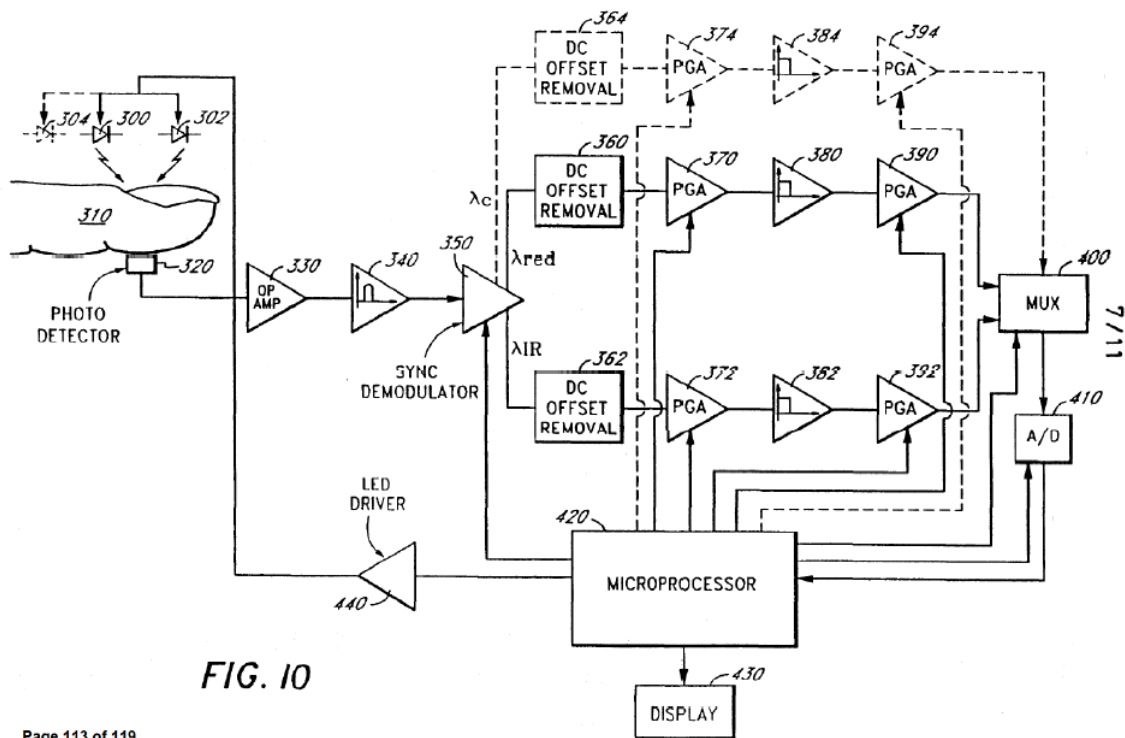


FIG. 10

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Figure 10 depicts a pulse oximetry monitor incorporating a processor with an adaptive noise canceler. *Id.* at 21. LEDs 300 and 302 emit red and infrared wavelengths which pass through finger 310 and are received by

² Citations are to the page numbers of the underlying Diab reference rather than the page numbers of the Exhibit.

photodetector 320. *Id.* at 66, 68. Photodetector 320 produces electronic signals corresponding to the attenuated red and infrared light signals. *See id.* at 66–67. After filtering and other processing, the signals are input to microprocessor 420 “for calculation of a noise reference signal via the processing technique of [Diab] and removal of undesired signal portions via an adaptive noise canceler.” *Id.* at 68–69.

We have reviewed all of Petitioner’s arguments and cited support but find no persuasive articulation of a reason with rational underpinnings as to why one would have found it obvious to combine the references’ teachings to arrive at the claimed subject matter. *See, e.g.*, Pet. 42–45.

Petitioner’s initial argument is that the two references are similar and have “complimentary” disclosures. *See* Pet. 42. Similarity might support a finding of analogous art, but does not explain why one would have combined the references’ teachings. Moreover, Petitioner does not explain adequately how the two references are “complimentary” or why that would have led a person of ordinary skill in the art to combine them.

Petitioner then argues that the references similarly disclose the assumptions and, therefore, “the claimed assumptions were obvious when viewing *Prosser* in light of *Diab*.” Pet. 42–43. First, the test for obviousness is whether the claimed invention as a whole would have been obvious to a person of ordinary skill, not whether particular features, i.e., the assumptions, would have been obvious. *See* 35 U.S.C. § 103. Second, Petitioner’s implied position that *Prosser* discloses the assumptions (*see* Pet. 43) is inconsistent with Petitioner’s earlier position that the differences between *Prosser*’s disclosure and the claimed invention are the claimed assumptions. *See* Pet. 37 (in articulating the basis of the obviousness

ground, stating: “[T]o the extent there is any doubt about whether *Prosser* addresses the claimed assumptions, that doubt can be readily resolved by viewing *Prosser* in light of *Diab*”). If *Prosser* already discloses the claimed assumptions, we fail to see why one would modify *Prosser* in view of *Diab* to have those assumptions; and if *Prosser* lacks the assumptions, we fail to see how any similarity between *Prosser*’s assumptions and *Diab*’s provides rational underpinning for a conclusion of obviousness.

Petitioner quotes from *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 419–20 (2007), for the proposition that a known problem can provide a reason for combining elements. Pet. 43. Petitioner, however, does not articulate adequately an application of this proposition. Petitioner merely asserts that the two references are focused on and attempting to solve the same problem, and argues that it would have been obvious to have “viewed” *Diab*’s assumptions in light of *Prosser*’s system. *Id.* at 43–44; *see* Ex. 1002 ¶¶ 55–56. Absent is an explanation as to why any problem would have prompted a modification of *Prosser*. *See* Pet. 43–44.

Petitioner also quotes from *KSR* regarding the proposition involving the use of a known technique that improves one device to improve a similar device. *Id.* at 44. Petitioner, however, does not argue affirmatively that the assumptions constitute a technique that improved *Diab*. *See id.* (“To the extent that those assumptions improved *Diab*’s techniques”); *see* Ex. 1002 ¶ 56 (same).

Lastly, Petitioner argues that *Prosser* would not be modified in any significant way, its principle of operation would not fundamentally change, and implementation of the modification would not require undue experimentation. Pet. 44–45. These arguments, again, do not explain why

one would have made the proposed modification.

Accordingly, we find Petitioner has not demonstrated that there is a reasonable likelihood that it would prevail in showing that the subject matter of the challenged claim 1 would have been obvious over Diab and Weinstein.

III. CONCLUSION

We determine Petitioner has not demonstrated there is a reasonable likelihood of establishing the unpatentability of claim 1 of the '034 patent.

IV. ORDER

For the foregoing reasons, it is

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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Patent 8,560,034 B1

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