

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENERAL ELECTRIC CO.,
Petitioner,

v.

UNIVERSITY OF VIRGINIA PATENT FOUNDATION,
Patent Owner.

Case IPR2017-00109
Patent RE45,725 E

Before KARL D. EASTHOM, TREVOR M. JEFFERSON, and
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

JEFFERSON, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

INTRODUCTION

On October 19, 2016, General Electric Co. (“GE”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 47–80 (“the challenged claims”) of U.S. Patent No. RE45,725 E (Ex. 1001, “the ’725 Patent”). Patent Owner University of Virginia Patent Foundation (“UVAPF”) timely filed a Preliminary Response (Paper 7, “Prelim. Resp.”).

We instituted an *inter partes* review on all challenged claims. Paper 10, “Inst. Dec.”). UVAPF filed a Patent Owner Response (Paper 13, “PO Resp.”), and GE filed a Petitioner Reply (Paper 18, “Pet. Reply”). UVAPF filed a sur-reply to GE’s reply (Paper 21, PO SR”) and GE filed a response to UVAPF’s sur-reply (Paper 23, “Pet. Resp. to SR”). The parties filed a Motion to Seal that is addressed below. An oral hearing was held on December 13, 2017. Paper 29 (“Tr.”).¹

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. As explained below, GE has shown by a preponderance of the evidence that the challenged claims of the ’725 Patent are unpatentable.

A. *Related Proceedings*

GE identifies the following matters as related to its Petition: (1) *Univ. of Va. Patent Found. v. Gen. Elec. Co.*, No. 3:14-cv-00051-nkm (W.D. Va.); and (2) three *inter partes* reviews (IPR2016-00357, IPR2016-00358, and IPR2016-00359) of U.S. Patent No. RE44,644 E (“the ’644 Patent”), a related patent. Pet. 1–2. Final Written Decisions have issued in IPR2016-00357, IPR2016-00358, and IPR2016-00359. *Gen. Elec. Co. v. Univ. of Va.*

¹ The parties raised objections to demonstrative exhibits presented at the oral hearing. Papers 26, 28. Upon review, all such objections are denied.

Patent Found., Case IPR2016-00357 (PTAB June 21, 2017) (“IPR2016-00357 FWD”); *Gen. Elec. Co. v. Univ. of Va. Patent Found.*, Case IPR2016-00358 (PTAB June 21, 2017) (“IPR2016-00358 FWD”); *Gen. Elec. Co. v. Univ. of Va. Patent Found.*, Case IPR2016-00359 (PTAB June 21, 2017) (“IPR2016-00359 FWD”). A decision denying rehearing in IPR2017-00357 was issued. *Gen. Elec. Co. v. Univ. of Va. Patent Found.*, Case IPR2016-00357 (PTAB Sep. 19, 2017) (“IPR2016-00357 Reh. Dec.”)

B. The ’725 Patent

The ’725 Patent relates to nuclear magnetic resonance imaging (“MRI”) technology. Ex. 1001, 1:52–56. In particular, the ’725 Patent relates to spin echo MRI, which provides “a wide range of useful image contrast properties that highlight pathological changes and are resistant to image artifacts from a variety of sources such as radio-frequency or static-field inhomogeneities.” *Id.* at 1:62–67.

In spin echo MRI, one or more spin echo magnetic resonance (“MR”) signals are generated after an initial “excitation radio-frequency (RF) pulse.” *See id.* at 2:1–6. Data about the imaged subject in k-space may be collected periodically in conjunction with a series of spin echoes (i.e., a spin echo train), using gradient magnetic fields for spatial encoding, to produce an image of the subject. *See id.* at 2:25–54. The spin echoes are generated using RF “refocusing” pulses, which are characterized by, among other things, a “flip angle.” *See id.* at 2:64–3:12. Conventional spin echo techniques at the time of the invention—including, for example, “fast spin echo” or “turbo spin echo” techniques—used high flip angle refocusing RF pulses, which limited the usable duration of the echo trains and, thus, the amount and/or quality of data obtained. *See id.* at 2:64–3:24.

Unlike most conventional spin echo techniques, which used constant flip angles, the '725 Patent describes the use of variable flip angles for the refocusing RF pulses. *Id.* at 3:66–4:6. According to the '725 Patent, variable flip angle pulse sequences according to the claimed invention can extend the duration of usable spin echo trains, which in turn can improve spatial resolution and/or reduce the time needed to acquire images. *Id.* at 4:6–11. Further, the variable flip angle sequences of the '725 Patent use flip angles that, typically, are less than the 180° flip angles common in conventional spin-echo techniques, permitting less power to be applied to human subjects and, thus, enhancing patient safety. *Id.* at 5:55–67.

C. Prosecution History of the '725 Patent

The '725 Patent is a reissue patent from U.S. Patent Application No. 14/053,190, which is a continuation of U.S. Patent Application No. 12/354,471 (“the '471 Application”). Ex. 1001, at [21], [63]. The '471 Application issued as the '644 Patent, which was a reissue of U.S. Patent No. 7,164,268 (“the '268 Patent”). *Id.* at [63]. The '268 Patent was issued on January 16, 2007, from a PCT application filed on December 21, 2001. *Id.* at [64]. The '268 Patent—and, thus, the '725 Patent—claims priority to U.S. Provisional Application No. 60/257,182 (“the '182 Application”), which was filed on December 21, 2000. *Id.* at [60].

D. Instituted Grounds of Unpatentability and Illustrative Claim

We instituted *inter partes* review on the grounds that claims 47–80 of the '725 Patent are unpatentable under 35 U.S.C. § 102 as anticipated by

Mugler 2000;² and that claims 47–80 of the '725 Patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Mugler 2000 and Mugler Overview.³ GE also relies on the Declaration of Professor Norbert J. Pelc (Ex. 1009).

UVAPF submits the Declarations of Dr. John P. Mugler, III (Ex. 2007), Dr. Berthold Kiefer (Ex. 2013), and Dr. Klaus Jürgen Hennig (Ex. 2023⁴ and Ex. 2025) as well as other evidence.

Claims 47, 57, 67, 73, 79, and 80 are independent claims, and all other challenged claims depend, directly or indirectly, from those independent claims. Independent claim 47 (Ex. 1001, 21:53–22:44) is illustrative:

47. A method of generating a spin-echo-train pulse sequence used in operating a magnetic resonance imaging apparatus configured for imaging an object, said method comprising:

providing a data-acquisition step based on said spin-echo-train pulse sequence, said data-acquisition step comprises:

providing an excitation radio-frequency pulse;

providing at least two refocusing radio-frequency pulses, each having a flip angle and phase angle,

wherein, in order to permit during said data-acquisition step lengthening usable echo-train duration, reducing power deposition and

² John P. Mugler III et al., *Three-Dimensional T2-Weighted Imaging of the Brain Using Very Long Spin-Echo Trains*, Proceedings of the Int'l Soc. for Magnetic Resonance in Med., 8th Meeting (Apr. 2000) (Ex. 1002, "Mugler 2000").

³ John P. Mugler III, *Overview of MR Imaging Pulse Sequences*, in MAGNETIC RESONANCE IMAGING CLINICS OF NORTH AMERICA: PHYSICS OF MR IMAGING 661–697 (Scott A. Mirowitz and J. Paul Finn eds., 1999) (Ex. 1005, "Mugler Overview").

⁴ Dr. Hennig's Declaration (Ex. 2023) is a copy of a declaration filed in *inter partes* review proceedings related to the '644 Patent, and does not address directly the '725 Patent.

incorporating desired image contrast into the signal evolutions, said flip angle is selected to vary, among a majority of the total number of said refocusing pulses applied during the echo train, by decreasing to a minimum value and later increasing in order to yield a signal evolution pertaining to the associated train of spin echoes of at least one first substance of interest in said object, with corresponding T1 and T2 relaxation times and spin density of interest, and in order to yield a signal evolution pertaining to the associated train of spin echoes of at least one second substance of interest in said object, with corresponding T1 and T2 relaxation times and spin density of interest

wherein said varying flip angle results in a reduced power deposition compared to the power deposition that would be achieved by using refocusing radio-frequency pulses with constant flip angles of 180 degrees,

wherein said signal evolutions result in a T2-weighted contrast in the corresponding image(s) that is substantially the same as a T2-weighted contrast that would be provided by imaging said object using a conventional spin-echo pulse sequence,

wherein an effective echo time corresponding to said spin-echo trains with said signal evolutions of said substances is at least twice an echo time of said convention spin-echo pulse sequence, and

wherein: said effective echo time corresponding to said spin-echo trains with said signal evolutions of said substances is at least on the order of 300 milliseconds; and/or the duration of said spin-echo trains with said signal evolutions of said substances is at least on the order of 600 milliseconds;

providing magnetic-field gradient pulses that perform at least one of encoding spatial information into at least one

of the radio-frequency magnetic resonance signals that follow at least one of said refocusing radio-frequency pulses and dephasing transverse magnetization associated with undesired signal pathways in order to reduce or eliminate a contribution of said transverse magnetization into sampled signals; and

providing data sampling, associated with magnetic-field gradient pulses that perform spatial encoding; and

repeating said data-acquisition step until a predetermined extent of spatial frequency space has been sampled.

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 Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016).

GE and UVA propose constructions for a number of terms in the challenged claims. Pet. 24–28; Prelim. Resp. 4–9. Our institution decision construed “effective echo time” as “the time period from the excitation RF pulse to the collection of data corresponding to substantially zero-spatial frequency (the center of k space).” Inst. Dec. 7–8.⁵ Neither party disputed this preliminary construction during trial, or provided any further argument or evidence regarding the proper construction of this term. Accordingly, for the same reasons explained in the Decision on Institution (Inst. Dec. 7–8),

⁵ We note that in IPR2016-00357, our Final Written Decision also construed the claim term “effective echo time” in the ’644 Patent as “the time period from the excitation RF pulse to the collection of data corresponding to substantially zero-spatial frequency (the center of k space).” *Gen. Elec. Co. v. Univ. of Va. Patent Found.*, Case IPR2016-00357, slip op. at 8 (PTAB June 21, 2017).

we maintain our earlier construction of this term. No other claim terms require express construction for purposes of this Final Written Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Level of Ordinary Skill

According to GE's expert witness, Dr. Norbert J. Pelc, a person of ordinary skill in the art would have had "significant working knowledge of MR spin-echo imaging, especially fast-spin-echo imaging," as well as "a Ph.D. in a physical science (e.g., electrical or biomedical engineering or medical physics) with experience in the development of MR imaging techniques, or an M.D. degree or an M.S. degree in a physical science with significant (3–5 years) of work experience in the development of MR imaging techniques." Ex. 1009 ¶ 92. UVAPF's expert witness, Dr. Klaus Jürgen Hennig, concurs generally with Dr. Pelc's description, but adds that a person of ordinary skill would have been

familiar with (1) using variable flip angles to extend the echo train length, to the extent that this technology was described in the art of the time; (2) preexisting spin-echo-train imaging techniques, such as RARE, fast-SE, and GRASE; and (3) techniques for extending the echo train length described in Alsop (Ex. 1004) and Hennig (Ex. 2024).

Ex. 2025 ¶ 8.

Based on Dr. Pelc's credible testimony, we find that a person of ordinary skill in the art would have met Dr. Pelc's description. We further find that Dr. Hennig's testimony on this issue does not differ materially from that of Dr. Pelc, and, in any event, our analysis in this Decision would be unchanged were we to apply Dr. Hennig's description.

C. Asserted Prior Art & Priority Date

1. Mugler 2000 as Prior Art under 35 U.S.C. § 102(b)

GE contends that the '725 Patent should not receive the benefit of the filing date of the '182 Application, and its effective priority date should be December 21, 2001, as a result. Pet. 6–8. As a result, according to GE, the Mugler 2000 reference is prior art under 35 U.S.C. § 102(b) because it was published in April 2000, more than one year earlier. *Id.* at 19. GE asserts that the written description of the '182 Application does not support sufficiently the challenged claims of the '725 Patent in several respects. Pet. 8–18.

In response, UVAPF argues that Mugler 2000 is not prior art under 35 U.S.C. § 102(b) because the claims do not provide adequate written description support for “effective echo time ratio” limitation in the challenged claims. PO Resp. 1–2, 4–9; *see* Pet. 15–18.

Our prior decisions in cases related to the '725 Patent concluded that Mugler 2000 is not prior art under § 102(a), but that it qualifies as prior art under § 102(b). *See* IPR2016-00357 FWD at 11–22; IPR2016-00357 Reh. Dec. at 2–8 (PTAB Sep. 19, 2017) (rehearing decision); IPR2016-00358 FWD at 9–21; IPR2016-00359 FWD at 9–20.

For a patent to claim priority to the filing date of its provisional application, the written description of the provisional application must be sufficient to support the relevant claims of the patent under 35 U.S.C. § 112. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)). Sufficient written description support requires providing enough information in the application to indicate to a person of ordinary skill that the inventor had possession of the full scope of

the claims. *In re Wertheim*, 541 F.2d 257, 262–64 (C.C.P.A. 1976). The disclosure need not recite the claimed invention *in haec verba*, but a disclosure that “merely renders the invention obvious” is insufficient. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc).

With respect to § 102(b), GE bears the burden to prove that Mugler 2000 is prior art under § 102(b) as part of its overall burden of persuasion to prove unpatentability. *See Dynamic Drinkware*, 800 F.3d at 1378. GE also bore the initial burden of production, but satisfied that burden by asserting that Mugler 2000 is prior art under § 102(b). *See id.* at 1379. The burden then shifted to UVAPF to produce evidence that the challenged claims of the ’725 Patent are entitled to an earlier priority date. *See id.* at 1380.

UVAPF does not dispute that Mugler 20000 was publicly presented, published and distributed as part of the conference proceedings in April 2000 (Pet. 19; Ex. 1009 ¶ 115). Instead, UVAPF argues that the ’182 Application provides sufficient written description for the effective echo time ratio limitation, which requires that “an effective echo time of the claimed pulse sequence ‘is at least twice’ either ‘an echo time of said conventional spin-echo pulse sequence’ (claims 47, 57, and 79) or ‘an effective echo time of said [TSE] pulse sequence or [FSE] pulse sequence’ (claims 67, 73, and 80).” PO Resp. 4–5. Specifically, UVAPF argues that the ’182 Application provides support for a spin-echo-train pulse sequence that produced images having T2-weighted contrast that is comparable to images produced with given flip angles, but that also use a longer echo-train duration than prior art techniques. PO Resp. 5–6. Thus, UVAPF points to the ’182 Application’s disclosure of limitations—namely, “echo train

duration” and “substantially the same contrast”— as written description support for the effective echo time ratio limitations. *Id.* at 5–8.

Our prior related decisions rejected UVAPF’s contention that the relationship between echo train duration and desired image contrast was sufficient to direct an ordinarily skilled artisan to the claimed echo train ratio recited in the ’725 Patent and provided sufficient written description support. *See* IPR2016-00357 FWD at 21–22 (PTAB June 21, 2017); IPR2017-00357 Reh. Dec. at 5. UVAPF has not provided sufficient or persuasive argument or evidence to reach a different conclusion in the present case.

UVAPF argues:

The ’182 Application compares the T2-weighted contrast between the images: The “***contrast characteristics appear very similar*** to those for conventional T2-weighted SE images (Fig. 4a).” *Id.* at 10 (emphasis added). The ’182 Application also explains that “the overall image quality for the very long spin-echo-train and conventional-SE images is similar” *Id.* The ’182 Application states that the echo time of the conventional spin-echo sequence was 80 ms and the effective echo time for the claimed sequence was 328 ms. Ex. 1014[,] Fig. 4. Thus, the effective echo time ratio for this example is 4.1. Decision (Paper 10) at 10.

. . . .

A person of ordinary skill understands that increasing the echo-train duration for the claimed pulse sequence necessarily increases the effective echo time that yields images having the same T2-weighted contrast. Thus, if the echo-train duration for the claimed pulse sequence, which the ’182 Application explains was 656 ms, is doubled to 1312 ms, for example, the effective echo time that generates images having substantially the same contrast as the images in Figures 4(a)-(d) will increase from 328 ms to approximately 500 ms. Ex. 2025 ¶ 15. Thus, the effective echo time ratio, which reflects the amount by which the echo-train duration has been extended while

generating images with substantially the same contrast, will have risen from 4.1 to 6.3. *Id.* The effective echo time of the claimed pulse sequence corresponding to a particular T2-weighted contrast must increase as the echo-train duration increases. *Id.* ¶ 14. The effective echo time ratio represents the increase in echo-train duration for which a particular T2-weighted contrast—that is substantially the same as that from a 180° flip-angle pulse sequence—is obtained, and thus directly reflects a primary objective of the invention in the '182 Application.

PO Resp. 8–9 (footnote omitted).

Patent Owner's argument is not commensurate with the scope of the construction for "effective echo time" as "the time period from the excitation RF pulse to the collection of data corresponding to substantially zero-spatial frequency (the center of k space)." This construction requires no particular image contrast or echo train duration.

In addition, UVAPF has not provided persuasive argument or evidence that supports its contention that "[a] person of ordinary skill [would have understood from the '182 Application] that increasing the echo-train duration for the claimed pulse sequence *necessarily* increases the effective echo time that yields images having the same T2-weighted contrast." PO Resp. 8 (emphasis added). UVAPF's expert testified that there is not a direct relationship between echo-train duration and effective echo time because the effective echo time may be set to any value to obtain a suitable image. Ex. 1048, 66:23–67:4, 68:23–69:4, 69:19–70:5; *see also* Ex. 1005, Fig. 9 (showing TE_{eff} set). UVAPF's argument that increasing the echo train duration necessarily increases the effective echo time for a suitable image rest on a series of assumptions and conditions that do not dictate effective echo time absent those assumptions. *See* Ex. 1048, 277:14–279:22 (ratio of TE_{eff} to echo-train duration is the same for the claimed sequence as for the

conventional sequence); Ex. 2025 ¶14 n.3 (“same signal evolution shape, scaled to be shorter or longer, is used.”); Ex. 1048, 280:13–281:16 (same); *id.* at 282:5–7 (same echo spacing); *id.* at 282:18–283:5 (four-step algorithm used to calculate flip angles); *id.* at 285:4–286:3, 296:3–24 (discussing assumptions and noting that they are not required). In addition, UVAPF’s expert admits that there are ways to increase or decrease echo-train duration that do not change the effective echo time of the claimed sequence. *Id.* at 301:18–302:2, 307:13–308:16.

UVAPF also has not shown persuasively that obtaining images with substantially the same contrast discloses the effective echo time ratios. The similar contrast characteristics discussed in the ’182 Application (PO Resp. 7–8) were not tied to echo train ratios and evidence shows that effective echo time duration is selectable and not subject to any particular ratio. Ex. 1048, 66:23–67:4, 68:23–69:4, 69:19–70:5; *see also* Ex. 1005, Fig. 9.

Despite UVAPF’s argument to the contrary (*see* PO Resp. 9–14), in our view, the operative facts here closely parallel those of *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000). In *Purdue Pharm*, the patent at issue claimed a method of treating pain by administering an opioid only once a day in an oral sustained release dosage form. *Purdue Pharma*, 230 F.3d at 1322. The relevant claims recited a ratio of “more than twice” between maximum plasma concentration of the opioid ($C_{\max}$) and the plasma level of the opioid 24 hours after administration (C_{24}). *Id.* The patentee argued the written description provided adequate support under § 112 because of two examples in the specification in which the $C_{\max}/C_{24}$ ratio was greater than two. *Id.* at 1326. The court, however, upheld the district court’s finding that the written description was insufficient:

Although the examples provide the data from which one can piece together the $C_{\max}/C_{24}$ limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the $C_{\max}/C_{24}$ ratio. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the $C_{\max}/C_{24}$ ratio as an aspect of the invention. . . . [T]he disclosure of the '360 patent discloses a multitude of pharmacokinetic parameters, with no blaze marks directing the skilled artisan to the $C_{\max}/C_{24}$ ratio or what value that ratio should exceed.

Id. The court held that the written description requirement was not met, stating that “[b]ecause the specification does not clearly disclose to the skilled artisan that the inventors of the '360 patent considered the $C_{\max}/C_{24}$ ratio to be part of their invention, it is immaterial what range for the $C_{\max}/C_{24}$ ratio can be gleaned from the examples when read in light of the claims.”

Id. at 1328. Likewise, here, nothing in the '182 Application would direct an ordinarily skilled artisan to the effective echo time ratios as an aspect of the invention. Even if UVAPF is correct that the effective echo time ratios claimed in the '725 Patent could be derived or calculated from information in the '182 Application, the '182 Application lacks any blaze marks directing the skilled artisan to make that calculation to arrive at the effective echo time ratios.

UVAPF argues that “[u]nlike the specification in *Purdue Pharma*, in which ‘neither the text accompanying the examples, nor the data, nor anything else in the specification emphasize[d]’ the plasma concentration ratio, the '182 Application explains that increasing the effective echo time ratio beyond prior art techniques is a primary objective of the invention as discussed above.” PO Resp. 10 (citing *Purdue Pharma*, 230 F.3d at 1326). UVAPF also argues that none of the examples in the specification in *Purdue*

Pharma were in the range, but examples in the '182 Application fall within the claimed range. PO Resp. 10–11 (citing *Purdue Pharma*, 230 F.3d at 1326).

In addition, UVAPF argues that the Board's decision in *MotionPoint Corp. v. Transperfect Global, Inc.*, CBM2014-00066, Paper 8 at 24 (PTAB July 23, 2014), rejected applying *Purdue Pharma* as requiring explicit identification of a feature as relevant or important, and instead endorsed the proper standard under *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575–76 (Fed. Cir. 1985), that a specification could provide adequate written description by describing a value for a feature and teaching that it could be adjusted to obtain other values. PO Resp. 11–12. We disagree.

The specification of the '182 Application does not direct a skilled artisan to any particular ratio, or range of ratios, between the effective echo time of the claimed pulse sequences and the echo time of a conventional spin echo sequence (or the effective echo time of a turbo spin echo or fast spin echo sequence). UVAPF does not identify any such blaze marks, and instead argues without citation that the "'182 Application makes clear that the effective echo train ratio is an important feature of the invention." PO Resp. 11. UVAPF asserts that a skilled artisan could have readily derived the ratios from the examples in the specification and relies on cases to support the adequacy of such disclosure. PO Resp. 11–12 (citing *Ralston Purina*, 772 F.2d at 1575–6; *Waddington N. Am., Inc. v. Sabert Corp.*, No. 09-4883 GEB, 2011 WL 1098996, at *3 (D.N.J. Mar. 22, 2011)). The cases cited by UVAPF each disclosed and emphasized the feature in question, a value for the feature, and an indication of the range for such values. *See id.*; Reply 4 n.3; *see also Ralston Purina*, 772 F.2d at 1576 (stating that "[t]he trial court also found that the parent [application], which disclosed [the

feature], indicated that [the feature] could be adjusted”). Indeed, the court in *Waddington* noted that the specification emphasized the importance of the feature and thus, distinguished the facts of that case from *Purdue Pharma*. *Waddington*, 2011 WL 1098996 at *6.

With respect to the ’182 Application, as in *Purdue Pharma*, “neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes” the effective echo time ratios. See *Purdue Pharma*, 230 F.3d at 1326. Thus, it is “immaterial what range for the [recited ratios] can be gleaned from the examples” because the specification does not clearly indicate the specific ratios recited in the claims are part of the invention. See *id.* at 1328; see, e.g., Ex. 1051, 190:25–191:14 (Dr. Hennig acknowledging that there is no indication of the specific TE_{eff} ratio using the variable flip angle method to the TE_{eff} obtained using a conventional SE or FSE sequence).⁶ We are not persuaded by and do not agree with UVAPF’s interpretation of *Purdue Pharma* as inapplicable. As discussed above, we also do not find that the specification of the ’182 Application “inherently” or sufficiently describes the effective echo time

⁶ As we stated in the IPR2016-00357 with respect to the ’644 patent and the ’182 Application:

[T]he ’182 Application does not emphasize echo time ratios, ascribe any significance to them, or even identify any such ratios. Although the specification reports an effective echo time of 328 ms for a variable flip angle sequence and an echo time of 80 ms for a conventional spin-echo sequence (among several other parameters), the ’182 Application does not compare those values, nor does it specify any ratio or other relationship between them.

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ratios by referring generically to extending echo train duration and suitable contrast images.

We do not agree with UVAPF's argument that the "at least twice" recitation in the claims is supported by prior art techniques in the Alsop reference. PO Resp. 14–17. UVAPF's argues that

[t]he '182 Application explains that the invention seeks to extend the echo-train duration beyond that obtained by Dr. Hennig's "constant, low flip angle" approach and Dr. Alsop's "pseudosteady-state" approach: "In this disclosure, we describe a method for lengthening the usable echo-train duration for spin-echo-train imaging substantially beyond that achievable with the [Hennig] or [Alsop] approaches." Ex. 1014 at 4. The '182 Application states that the echo-train duration for the brain images shown in Alsop was 400 ms. *Id.* ("An 80-echo train with a duration of 400 ms and asymptotic flip angles ranging from 17° to 90° were used."). The '182 Application also explains that the maximum echo-train duration typically used for 180° flip-angle pulse sequences is 200 ms ($\frac{1}{2}$ of Alsop's echo-train duration) to 300 ms ($\frac{3}{4}$ of Alsop's echo-train duration)

PO Resp. 14–15. UVAPF relies on the knowledge of a person of ordinary skill in the art understanding that Alsop describes an effective echo time ratio of 1.3 to 2 based on the '182 Application's discussion of Alsop. PO Resp. 15. We are also not persuaded by UVAPF's argument that a person of ordinary skill in the art would understand the "inherent upper limitation of the 'at least twice' limitation is equal to the ratio of T1/T2" (PO Resp. 17–18 (citing Ex. 2023 ¶ 61; Ex. 2025 ¶ 16), or readily derive the range of the effective echo time ratio (PO Resp. 19–23). We are also not persuaded that the effective echo time has a sufficient correspondence to the T2 relaxation times in the prior art that would provide written description support for the claimed ratio of at least twice, given that Patent Owner's arguments and

evidence show variances. *See* PO Resp. 16 & n.5; Ex. 2023 ¶ 58; Ex. 2025 ¶ 18.

As discussed above, UVAPF has not established a connection between effective echo-train duration and the effective-echo-time ratio limitation. Whether a person of ordinary skill could derive the echo time ratio limitations from a discussion of admitted prior art in the '182 Application is immaterial when, as here, the disclosure does not identify, or direct a skilled artisan to, the recited echo time ratio as part of the claimed invention. *See Purdue Pharma*, 230 F.3d at 1328. In addition, UVAPF acknowledged the '182 Application does not identify or highlight the effective echo times or echo time ratios of any of the prior art references. IPR2016-00357 FWD at 22. Finally, we agree with GE that UVAPF's expert acknowledges that ALSOP discloses effective echo time ratios that approach five, not two. Ex. 1048, 244:25–246:10 (stating that the Alsop figure shows a ratio that is nearly 5 which is much higher than two); Pet. Reply 10–13.

We are not persuaded by UVAPF's arguments that Alsop's disclosure is inapplicable because the resulting images based on theoretical curves were not shown to generate useable images comparable to T2-weighted contrast images from a 180° flip angle pulse sequence as required by the challenged claims. PO SR. 2–5. We agree with GE that Dr. Hennig's declaration supports that the images produced by Alsop were substantially the same contrast (Ex. 2025 ¶ 21) and that Dr. Hennig's testimony belies UVAPF's contentions (Ex. 1048, 226:18–25, 244:25–245:11, 245:23–246:4; 257:8–10). Pet. Resp. to SR 3–4. Furthermore, Dr. Mugler's testimony supports GE's contention. Pet. Resp. to SR 4 (citing Ex. 1049, 139:22–140:6; 141:15–18 (admitting ratios above 2 are shown in Figure 3 of Alsop)).

Finally, UVAPF's arguments rely on Dr. Alsop's "pseudosteady-state" approach as maintaining desired image contrast in support of the argument that the '182 Application explains that prior art techniques obtain an effective echo time ratio approaching twice. PO Resp. 14–17 (citing Ex. 2025 ¶¶ 20, 21). Thus, we find the Alsop's teachings applicable.

Based on the foregoing, UVAPF has not demonstrated adequate written description support in the '182 Application for the echo time ratio limitations of the challenged claims in the '725 Patent. Thus, the challenged claims of the '725 Patent are not entitled to the priority date of the '182 Application. As a result, GE has demonstrated by a preponderance of the evidence that Mugler 2000 is prior art under § 102(b) as it was published April 2000, which is more than one year before the priority date of the '725 Patent, i.e., December 21, 2001.

GE contends that the challenged claims lack written description support because they "omit[] the entirety of the four-step algorithm for determining flip angles." Pet. 9. GE also contends that the challenged claims lack written description support for (1) "providing magnetic-field gradient pulses that perform . . . encoding spatial information into at least one of the radio-frequency magnetic resonance signals that follow at least one of said refocusing radio-frequency pulses" and (2) "providing magnetic-field gradient pulses that perform . . . dephasing transverse magnetization associated with undesired signal pathways in order to reduce or eliminate a contribution of said transverse magnetization into sampled signals." Pet. 12–14; Pet. Reply 18–20. Because we find Mugler 2000 prior art under § 102(b), we do not reach the merits of these arguments.

2. *Mugler 2000 as Prior Art under 35 U.S.C. § 102(a)*

An inventor's own work is not prior art under § 102(a). *See Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014); *In re Katz*, 687 F.2d 450, 454 (CCPA 1982). In determining whether a reference is the work of the named inventor(s), the relevant inquiry is whether the relevant content of the reference—such as “the methods, detailed results, statistical analysis and discussion,” or “the design, trial, and analysis of results”—was solely the work of the inventor(s). *See Allergan*, 754 F.3d at 969. For example, an article may be solely the work of an inventor if the remaining co-authors were merely students performing tasks under the inventor's direction and supervision. *See Katz*, 687 F.2d at 455–56.

Mugler 2000 lists three people as authors, Drs. Mugler, Brookeman, and Kiefer. Ex. 1002. Drs. Mugler and Brookeman are the named inventors of the '725 Patent. Ex. 1001, 1. Drs. Mugler and Kiefer provided declarations under oath that Dr. Kiefer's involvement in Mugler 2000 was limited to providing access to MR scanners and other resources, and that the methods, results, analyses, and discussion in Mugler 2000 were not Dr. Kiefer's work. Ex. 2007 ¶ 5; Ex. 2013 ¶ 3.

GE contends that Mugler 2000 is authored by another, Dr. Kiefer, and therefore prior art under § 102(a). Pet. 19–20. Our Institution Decision reserved this issue for trial. Inst. Dec. 15.

Following discovery, GE argues

[n]ew evidence in this proceeding establishes that the non-inventor-author of Mugler 2000, Dr. Kiefer, assigned the task to Dr. Mugler that led to Mugler 2000 and contributed critical technology to the methods of Mugler 2000 that permitted Mugler 2000's high-quality resulting images. Other new evidence also establishes that MR scientists working under Dr. Kiefer's direction contributed to the methods and detailed

results in Mugler 2000 and that the email evidence that the Board previously found ambiguous actually pertains to Mugler 2000.

Pet. Reply 21; *see* Ex. 1047, 62:4–63:6. GE contends that Dr. Kiefer’s deposition testimony belies the misleadingly worded declarations from Drs. Mugler and Kiefer, and support that Dr. Kiefer, defined the research task from Dr. Mugler’s 1999 visit (Ex. 1047, 62:4–63:6, 77:14–15); contributed key aspects on gain switching that improved image quality in Mugler 2000 (Ex. 2010, 1); and referred Dr. Mugler to sources for necessary computer code (Ex. 1049, 66:2–65:8). Pet. Reply 21–23. Finally, GE also argues that the emails found insufficient in IPR2017-00357, were shown to be generally related to Mugler 2000. Pet. Reply 24.

Upon review of the entire record, we determine on the full record that Mugler 2000 is not the work of another for purposes of § 102(a). Although Dr. Kiefer refers to “tasks” he defined in his deposition, the context and totality of the evidence does not indicate persuasively that he created the methods, detailed results, and discussion in Mugler 2000. Ex. 1047, 62:4–63:6, 77:14–15. Indeed, the evidence supports that Dr. Kiefer was tasked with working with developers like Dr. Mugler and did not write or edit the content of Mugler 2000. Ex. 2008; Ex. 2009; Ex. 1047, 82:17–83:12, 93:2–94:14. Although GE marshals circumstantial evidence that Mugler 2000 is the work of Dr. Kiefer based on emails and technical assistance provided to Dr. Mugler, the evidence, including the declarations of Drs. Kiefer and Mugler, does not establish sufficiently the Dr. Kiefer contributed to the content of Mugler 2000 or refute the declarations of Drs. Mugler and Kiefer. Accordingly, Mugler 2000 is not prior art under § 102(a).

D. Unpatentability Under § 102(a), § 102(b), and § 103

To anticipate a claim, a single prior art reference must disclose each and every limitation of the claim, either expressly or inherently. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). A feature is disclosed inherently if it is *necessarily* present in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

GE challenges claims 47–80 as obvious in light of Mugler 2000 and Mugler Overview because it contends that Mugler Overview teaches expressly each limitation that it contends Mugler 2000 discloses inherently for anticipation purposes. Pet. 28–42. GE further contends that each of the challenged claims are obvious in view of the combined teachings of Mugler 2000 and Mugler Overview. Pet. 41–42.

UVAPF does not contest that Mugler 2000 invalidates or renders obvious the challenged claims of the ’725 Patent.⁷ Instead, UVAPF challenges whether Mugler 2000 is prior art under 102(a) or 102(b). See PO Resp. 1–3. Because we determine that Mugler 2000 is prior art under § 102(b), for the reasons discussed below, we find that GE has shown by a preponderance of the evidence that Mugler 2000 discloses the limitations of

⁷ Our Order instituting trial cautions “that any arguments for patentability not raised in the response will be deemed waived.” Paper 11, 6 (Due Date 1); see *In re Nuvasive*, 842 F.3d 1376, 1379–82 (Fed. Cir. 2016).

claims 47–80 and that Mugler 2000 and Mugler Overview teach the limitations of claims 47–80.

1. Anticipation: Mugler 2000

GE contends Mugler 2000 anticipates independent claim 47. The Petition sets forth detailed contentions and supporting evidence demonstrating that Mugler 2000 discloses each limitation of claim 47 either expressly or inherently. Pet. 28–35.

For example, the Petition cites Figure 1 of Mugler 2000, and its accompanying explanation, as disclosing flip angles for a sequence of 160 refocusing RF pulses. *Id.* at 30 (citing Ex. 1002, 1, Fig. 1). Figure 1 of Mugler 2000 is reproduced below:

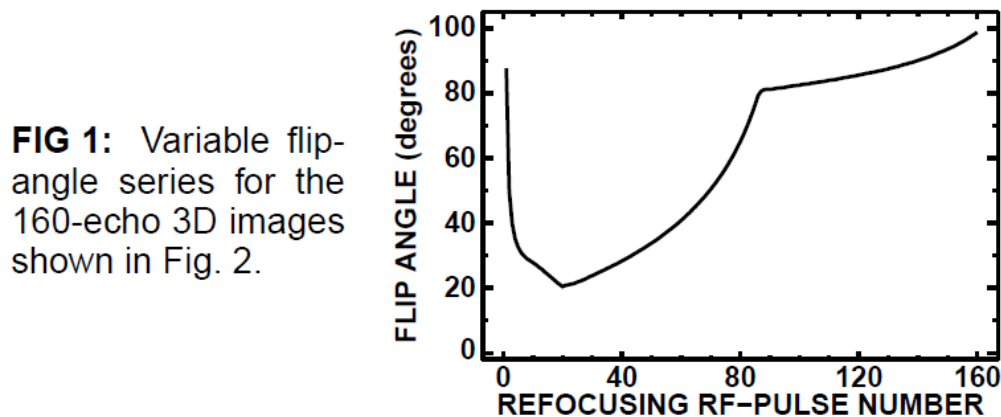


Figure 1 is a graph of the flip angles of each refocusing pulse in a variable flip angle pulse sequence. Ex. 1002, 1. Dr. Pelc testifies that all refocusing RF pulses necessarily have both a flip angle and phase angle. Ex. 1009 ¶ 140. Thus, according to GE, Mugler 2000 discloses the recited step of “providing at least two refocusing radio-frequency pulses, each having a flip angle and phase angle.” Pet. 30. Additionally, GE relies on Figure 1 as disclosing refocusing pulse flip angles varying “by decreasing to a minimum value and later increasing,” as recited in claim 47. *Id.* at 31.

The Petition also explains how Mugler 2000 discloses the recited limitation that the varying flip angles of the refocusing RF pulses are selected “to yield a signal evolution pertaining to the associated train of spin echoes” for a first and second substance of interest, each with “corresponding T1 and T2 relaxation times and a spin density of interest.” *Id.* at 31–32. As the Petition notes (*id.*), Mugler 2000 states that “variable-flip-angle refocusing RF-pulse series were calculated for several prescribed signal evolutions” for brain tissues. Ex. 1002, 1. Further, Dr. Pelc testifies that the contrast between light and dark areas shown in the MR images in Mugler 2000 discloses signal evolutions for multiple different brain tissues, and that each of these tissues necessarily have an inherent T1 relaxation time, T2 relaxation time, and spin/proton density. Ex. 1009 ¶¶ 146–148 (citing Ex. 1002, Fig. 2).

With respect to the limitation that the contrast in a resultant T2-weighted image be “substantially the same” as the contrast that would be provided by imaging the same object using a conventional spin-echo pulse sequence, the Petition notes the disclosure in Mugler 2000 that the variable flip angle sequence may “provide clinically useful contrast characteristics that appear very similar to those for conventional T2-weighted [spin echo] images.” Pet. 33 (citing Ex. 1002, 1, Fig. 2) (emphasis omitted).

As the Petition notes, Mugler 2000 further discloses that the variable flip angle sequence yielded an effective echo time of over 300 ms with an echo train duration of over 600 ms, with a specific example of 328 ms and 656 ms respectively. Pet. 33–34 (citing Ex. 1002, 1, Fig. 2); *see* Ex. 1009 ¶ 151. According to Petitioner and Dr. Pelc, Mugler 2000 compares this sequence and the resulting images to those of a conventional spin echo sequence with an echo time of 80 ms. Pet. 33; Ex. 1009 ¶ 151. Based on

this evidence, GE argues Mugler 2000 discloses the limitations of claim 47 that require an effective echo time “at least twice” the echo time of a conventional spin echo sequence, and which is “on the order of 300 milliseconds.” Pet. 33–34.

With respect to the “magnetic-field gradient pulses” limitations, the Petition relies on the disclosure in Mugler 2000 of a “phase-encoding direction” corresponding to the variable flip angle pulse sequence’s echo train. Pet. 34 (citing Ex. 1002, Fig. 2). According to Dr. Pelc, a person of ordinary skill would understand Mugler 2000 to be referring to magnetic field gradient pulses encoding spatial information into the MR signals following the refocusing RF pulses in the echo train. Ex. 1009 ¶ 152. Dr. Pelc also testifies that all MRI pulse sequences necessarily involve encoding spatial information into the MR signals using magnetic field gradient pulses. *Id.* ¶ 153 (citing Ex. 1005, 661).

On the full record, GE has demonstrated by a preponderance of the evidence that Mugler 2000 discloses each limitation of claim 47 either expressly or inherently. Thus, GE has proven by a preponderance of the evidence that claims 47–80 are anticipated by Mugler 2000.

2. Obviousness: Mugler 2000 and Mugler Overview

GE challenges claims 47–80 as obvious in light of Mugler 2000 and Mugler Overview because it contends that Mugler Overview teaches expressly each limitation that it contends Mugler 2000 discloses inherently for anticipation purposes. Pet. 41–42. For example, GE explains that Mugler Overview includes express teachings of a data acquisition step (Ex. 1005, 661–662, Fig. 1), excitation RF pulses (*id.* at 661), RF pulses with flip angles and phase angles (*id.* at 684), applying gradient pulses to

encode spatial information (*id.* at 661), and data sampling (*id.*). Pet. 42; *see* Ex. 1009 ¶¶ 192–197. For teachings of the remaining claim limitations, GE relies on the same arguments as it presented for anticipation to show that Mugler 2000 discloses those limitations expressly. *See* Pet. 41–42.

Relying on Dr. Pelc’s testimony, GE further asserts that a person of ordinary skill in the art would have been motivated to combine the relevant teachings of Mugler 2000 and Mugler Overview because both references are in the same field, both relate to fast spin echo MRI, both share a common author, and Mugler Overview provides a general overview of MRI pulse sequences that a person of ordinary skill would have been motivated to consult for background information relating to the MRI pulse sequences of Mugler 2000. *See* Pet. 41–42 (citing Ex. 1009 ¶ 191).

Based on the full record, GE has shown by a preponderance of the evidence that Mugler 2000 and Mugler Overview teach the limitations of claims 47–80. GE has proven by a preponderance of the evidence that claims 47–80 are obvious in view of Mugler 2000 and Mugler Overview.

E. UVAPF’s Motion to Seal (Paper 19)

UVAPF moves to seal certain portions of deposition testimony by Dr. Mugler (Ex. 2027). Paper 19, 1–11. AT UVAPF’s request, GE filed a redacted version of Exhibit 2027 as Exhibit 1049. GE filed a non-opposition to UVAPF’s motion to seal. Paper 22.

According to UVAPF, the testimony at issue is similar to testimony the Board previously sealed following UVAPF’s motion in IPR2016-00359 and for which GE did not oppose a motion to expunge. IPR2016-00359 FWD at 33–34; Paper 60 (IPR2016-00359). UVAPF argues that the testimony should be excluded because it is cross-examination testimony that

exceeds the scope of Dr. Mugler's direct testimony in violation of 37 C.F.R. § 42.53(d)(5)(ii). Paper 19, 4.

We note that none of the testimony at issue was directly relied on for any determination in this case. Thus, whether this testimony is excluded would have no effect on the outcome of this proceeding or on any aspect of the present Decision. We also agree that this testimony is similar to testimony previously sealed by the Board. Further, GE has already filed a redacted version of Exhibit 2027. We also note that the parties have agreed to adopt the Default Protective Order in the Office Patent Trial Practice Guide, 77 Fed. Reg. 48771 and attached as Appendix A to UVAPF's motion to seal. Paper 22, 5. Accordingly, we grant GE's motion to seal Exhibit 2027.

In addition, because there is an expectation that information will be made public where the information is identified in a final written decision, confidential information that is subject to a protective order ordinarily would become public 45 days after final judgment in a trial, unless a motion to expunge is granted. 37 C.F.R. § 42.56; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). A party who is dissatisfied with this Final Written Decision, however, may appeal this Decision pursuant to 35 U.S.C. § 141(c), and has 63 days after the date of this Decision to file a notice of appeal. 37 C.F.R. § 90.3(a).

In view of the above, the time period for filing a motion to expunge is extended to 90 days after final judgment in this trial. *See* 37 C.F.R. § 42.5(b). If an appeal is taken, this time period shall be further extended to 45 days after the appeal process has concluded. *See id.* During this period, all information sealed in this case shall remain under seal. The record for

the instant proceeding will be preserved in its entirety, and the confidential documents will not be expunged or made public, pending possible appeal.

SAS INSTITUTE INC. v. IANCU

The Supreme Court issued its decision on April 24, 2018, in *SAS Institute Inc. v. Iancu* concerning final written decisions issued by the Board addressing all claims a petitioner challenged in a petition. *SAS Institute Inc. v. Iancu*, No. 16-969, 2018 WL 1914661 (April 24, 2018). To the extent either GE or UVAPF believes that the Court's decision in *SAS Institute* requires additional consideration in this proceeding, the party may file a rehearing request pursuant to 37 C.F.R. § 42.71(d).

CONCLUSION

For the foregoing reasons, Petitioner has shown by a preponderance of the evidence that the challenged claims of the '725 Patent are unpatentable.

ORDER

It is

ORDERED that the challenged claims of the '725 Patent are held unpatentable as follows:

- (1) claims 47–80 as anticipated under 35 U.S.C. § 102(b) by Mugler 2000; and
- (2) claims 47–80 as obvious under 35 U.S.C. § 103(a) in view of Mugler 2000 and Mugler Overview;

FURTHER ORDERED that UVAPF's Motion to Seal (Paper 19) is *granted* as set forth above;

FURTHER ORDERED that the proposed Protective Order (Paper 19, Appendix A) is entered;

FURTHER ORDERED that the information sealed in this Decision remain under seal, and the record preserved, until 90 days after final judgment in this trial or, if an appeal is taken, until 45 days after the appeal process has concluded; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

David Pollock
Jonathan Detrixhe
REED SMITH LLP
dpollock@reedsmith.com
jdetrixhe@reedsmith.com

PATENT OWNER:

Rodney L. Sparks
UNIVERSITY OF VIRGINIA PATENT FOUNDATION
rodney@uvapf.org

Ari Rafilson
Joseph DePumpo
SHORE CHAN DEPUMPO LLP
jdepumpo@shorechan.com
arafilson@shorechan.com