

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTEC INC.

Petitioner

v.

FRED HUTCHINSON CANCER CENTER

Patent Owner

IPR Trial No. IPR2023-00760

U.S. Patent No. 9,987,308

Issue Date: June 5, 2018

Title: Method and Compositions for Cellular Immunotherapy

**PETITIONERS' REQUEST FOR REHEARING OF INSTITUTION
DECISION**

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Pursuant to 37 C.F.R. § 42.71(d), Petitioner respectfully requests rehearing of the Board’s Decision Denying Institution, Paper 10 (“Decision”) for Ground 1. A request for rehearing should be granted “if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors.” *Sand Revolution II, LLC v. Continental Intermodal Grp. – Trucking LLC*, IPR2019-01393, Paper 24 at 4, 2020 WL 3273334 at 2 (PTAB June 16, 2020).

It is undisputed that Singh-1 taught how to make a CAR T cell composition that had immunophenotype characteristics within the scope of claim 1 of the ’308 patent. Patent Owner only disputed whether the disclosed composition in Singh-1 satisfied the claim preamble of “[a]n adoptive cellular immunotherapy composition,” which it argued required “*therapeutic effect in vivo* by causing or mediating an immune response.” POPR at 25. In its Sur-Reply, Patent Owner then argued, improperly for the first time, that Singh-1 was not “enabled” for purposes of anticipation because Singh-1 lacks *in vivo* data. Sur-Reply at 5-6. The Board agreed in its Decision. Decision at 22. This conclusion is legally and factually incorrect.

This conclusion is legally erroneous because a long line of Federal Circuit decisions has held that “[t]he enablement requirement for prior art to anticipate under section 102 **does not require utility**, unlike the enablement requirement for

patents under section 112.”¹ *Impax Lab’ys v. Aventis Pharms.*, 468 F.3d 1366, 1381 (Fed. Cir. 2006), citing multiple Federal Circuit and CCPA decisions, including *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005) (“proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation.”); *In re Schoenwald*, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (“it is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim”); *In re Donohue*, 632 F.2d 123, 126 n. 6 (Cust. & Pat. App. 1980) (“proof of utility is not a prerequisite to availability of a prior art reference under 35 U.S.C. § 102(b)”). Simply put, enablement for purposes of anticipation does not require a reasonable expectation of successful efficacy: “[T]he effectiveness of the prior art is not relevant. Rather, the proper issue is whether the [prior art] is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art **to carry out the invention.**” *Impax*, 468 F.3d at 1383.

In *Rasmusson*, for example, the claims at issue were methods of treating prostate cancer by administering finasteride. 413 F.3d 1318, 1320 (Fed. Cir. 2005). The Board had held that prior art lacked an enabling disclosure because “there was no reasonable scientific basis for a person of ordinary skill in the art to conclude

¹ All emphasis is added, unless otherwise indicated.

that the claimed method would be effective in treating prostate cancer, and that given the lack of proof provided in the [prior art] publication itself, a person of ordinary skill in the art...would not have believed that the method described in [prior art] EP '383 would be effective.” *Id.* at 1326 (cleaned up). The Federal Circuit reversed, explaining that “proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation” and “anticipation does not require actual performance of suggestions in a disclosure.” *Id.*

Here, the Decision was legally incorrect in holding that Singh-1 was not enabled for purposes of anticipation because Singh-1 did not disclose *in vivo* data or other teachings demonstrating *in vivo* utility, i.e., efficacy. It is undisputed that Singh-1 disclosed how to make a CAR T composition that, after five weeks of culture and expansion, satisfied all the immunophenotype characteristics recited in claim 1 of the '308 patent. Petition at 21-22, citing Ex. 1003 at 2961, 2963; Reply at 2. The same five-week composition would had approximately 4×10^8 T cells with balanced amounts of CAR⁺ CD4 and CAR⁺ CD8 cells. Ex. 1003 at Figure 4A (showing “Viable T-cell number” of approximately 8×10^8 at 35 days, i.e., 5 weeks) and Figure 4B (showing “Total CAR⁺” to be approximately 50% and similar percentages of CD4⁺CAR⁺ and CD8⁺CAR⁺ at 35 days); Reply at 4. It is also undisputed that the Singh-1 authors believed these were “clinically meaningful numbers.” Petition at 36-37 (“culture and expansion to clinically meaningful

numbers at five weeks”); Decision at 19, citing Ex. 1003 at 2962, 2964. Nor can it be disputed that these amounts of CAR T cells fall squarely within the ’308 patent’s disclosure of a “treatment-effective amount of cells,” which is “include[es] 10^8 or 10^9 cells.” ’308 patent, 18:36-40. Singh-1 showed that its CAR T cells “were able to lyse CD19⁺ targets” with *in vitro* efficacy data. Ex. 1003 at 2968-69, Figure 5. No more is required for enablement for purposes of anticipation under controlling precedent, *i.e.*, Singh-1 sufficiently “enable[s] a person of ordinary skill in the art to carry out the invention.” *Impax*, 468 F.3d at 1381. As the Federal Circuit decisions make clear, Singh-1 was not required to demonstrate *in vivo* therapeutic utility with data or other teachings. Because Patent Owner raised the enablement argument for the first time in its Sur-Reply, Petitioner was unable to address it before the Board’s decision.

Although not necessary to find that Singh-1 is enabled for purposes of anticipation, the Board should also reconsider its factual finding that Singh-2 invalidates Singh-1’s conclusions, and in particular, Singh-1’s conclusion that its CAR T composition had “clinical meaningful numbers.” Petitioner’s Reply explained that the disclosed Singh-1 CAR-T composition was materially different than the Singh-2 CAR-T composition that Patent Owner argued would fail *in vivo*. Reply at 1, 3-5. Singh-1 reported the percentage of CAR⁺ CD8⁺ T cells in its composition to be 34% of the overall population and 42% of CD8⁺ T cells. *Id.* But

Singh-2 disclosed that its composition expressed a CAR in only 1% of CD8⁺ T cells. Patent Owner never disputed these differences. *Id.*

The mere fact that Singh-2 reported a benefit in using IL-21 during its culturing process does not undo that Singh-1 disclosed a CAR T composition that had sufficient CAR⁺ CD8⁺ T cells despite not using IL-21. As Petitioner's Reply noted, the culturing processes disclosed in Singh-1 and Singh-2 were different in several ways. Reply at 5. More importantly, claim 1 of the '308 patent has no requirement that the claimed CAR T composition be made using IL-21 in the culture medium. Even though IL-21 was not used during the culture medium, it is indisputable that Singh-1 disclosed a CAR T composition that satisfied all immunophenotype characteristics recited in claim 1 of the '308 patent and had more than sufficient amounts of CAR⁺ CD8⁺ T cells. Singh-2 does not undermine Singh-1 as an enabled anticipatory reference.

I. THE BOARD'S DECISION RELIED ON AN ERRONEOUS INTERPRETATION OF LAW CONCERNING ENABLEMENT FOR PURPOSES OF ANTICIPATION

The Board construed “[a]n adoptive cellular immunotherapy composition” in the preamble to mean “a composition comprising adoptively transferred cells that has *therapeutic* effect *in vivo* by causing or mediating an immune response.” Decision at 17. In holding that Singh-1 was not enabled, the Decision relied on Singh-1's lack of “*in vivo* data” showing that its CAR-T cell composition was

therapeutically effective. *Id.*, 20-22, 25-27. This was legally erroneous because the Federal Circuit has held repeatedly that “proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation.” *Rasmusson*, 413 F.3d at 1326. “The enablement requirement for prior art to anticipate under section 102 does not require utility, unlike the enablement requirement for patents under section 112.” *Impax*, 468 F.3d at 1381. “[A] disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility...is...entirely adequate to anticipate.” *In re Schoenwald*, 964 F.2d 1122, 1124 (Fed. Cir. 1992).

In its Reply, Petitioner cited *Ex parte Kao*, No. 2008-5150, 2009 WL 1162439 (B.P.A.I. Apr. 29, 2009), which relies on Federal Circuit precedent, for the point that anticipation does not require *in vivo* data. Reply at 7-8. In Sur-Reply, Patent Owner argued for the first time that *Kao* was distinguishable because the prior art in *Kao* was “enabled” whereas Singh-1 was not. Sur-Reply at 6. Patent Owner had never before argued that Singh-1 was not enabled for purposes of anticipation. The Board has held it is improper for a patent owner to raise enablement arguments for the first time in sur-reply. *See Applied Materials, Inc. v. Ocean Semiconductor LLC*, IPR2021-01342, Paper 61 at 99, 2023 WL 1804826 at *41 (2023) (“strik[ing] the argument that the prior art is not enabled” made in sur-reply because it was not made in the patent owner response).

Many controlling Federal Circuit decisions have held that a prior-art reference will anticipate a composition claim even if the reference does not contain any data demonstrating a claimed utility or efficacy. Indeed, this is consistent with the principle that one cannot obtain a new composition patent by claiming a pre-existing composition, regardless of “discovery of an unobvious property” and “including the assertedly different properties in the claims.” *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990).

In *Spada*, the Federal Circuit affirmed a Board holding that pending composition claims were anticipated. 911 F.2d at 705, 709. The claims at issue were to a “pressure sensitive adhesive composition” comprising certain polymers. *Id.* at 706. The prior art (Smith) disclosed the claimed polymers but did “not show or suggest that his polymer latexes can form a normally tacky pressure-sensitive adhesive” that was a claimed property. *Id.* at 707. The Federal Circuit affirmed the holding of anticipation, explaining that “[w]hen the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art.” *Id.* at 709.

In *Rasmusson*, the Federal Circuit reversed a Board holding that anticipatory prior art was not enabled. 413 F.3d 1318, 1320 (Fed. Cir. 2005). The claims at issue were to “method[s] of treating prostatic carcinoma in animals” using

finasteride. *Id.* at 1321-22. The prior art (“EP ’383”) disclosed finasteride and methods of using it to treat prostate cancer, but failed to demonstrate with data that finasteride actually was therapeutically effective *in vivo*. *Id.* at 1325-26. The Board held that the prior art was not enabled for two reasons: First, “there was no reasonable scientific basis for a [POSA] to conclude that the claimed method would be effective in treating prostate cancer.” *Id.* at 1326. Second, “given the lack of proof provided in the [prior art] EP ’383 itself, a [POSA] would not have believed that the method described in the [prior art] EP ’383 would be effective.” *Id.* The Federal Circuit reversed, holding that “those findings are insufficient to support the Board’s conclusion that the [prior art] is not an enabling reference for purposes of anticipation.” *Id.* The court explained that “proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation,” nor does anticipation even “require actual performance of suggestions in a disclosure.” *Id.*

In *Impax*, the Federal Circuit reversed a district court holding that anticipatory prior art was not enabled. 468 F.3d 1366, 1383 (Fed. Cir. 2006). The claims at issue recited “[a] method for treating a mammal with [ALS], comprising the step of administering to said mammal in recognized need of said treatment an effective amount of [riluzole]...” *Impax*, 468 F.3d at 1372. A prior-art patent disclosed compounds and stated that they “are active with respect to glutamate-

induced convulsions, and are hence useful in the treatment and prevention of...neurological conditions in which glutamate may be implicated, such as...[ALS].” *Id.* at 1379. The district court found that the prior-art patent did not anticipate because its disclosure “was not enabling at least in part because there was no evidence that it would be ‘effective.’” *Id.* at 1383. The Federal Circuit reversed, stating that “a section 102 prior art reference does not have to be ‘effective’ to be enabling and thus anticipating.” *Id.* Citing *Rasmusson*, the court held that “the effectiveness of the prior art is not relevant. Rather, the proper issue is whether the [prior-art] is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.” *Id.*

Here, it is undisputed that Singh-1 is a peer-reviewed research article that fully discloses a method of manufacturing the CAR-T cell composition that had all immunophenotype characteristics of claim 1 of the ’308 patent and states that the intended use of this composition is for clinical trials. Petition at 21-22, 32-35.

For purposes of enablement under the anticipation standard, Singh-1 is not required to have *in vivo* data (or other teachings) demonstrating utility or efficacy. Singh-1 sufficiently indicates that its disclosed CAR T composition is intended for clinical use, i.e., therapeutically *in vivo*. Singh-1 disclosed that its process “results in efficient and stable CAR gene transfer, which can be numerically expanded to

clinically meaningful numbers within 4 weeks . . . and with the outgrowth of CD8⁺ and CD4⁺ CM and effector CAR⁺ T-cell subpopulations.” Ex.1003 at 2962; Decision at 19; Petition, 21, 33, 36-37. The Singh-1 composition had “CD4⁺ and CD8⁺ CAR⁺ T cells [of] clinically meaningful numbers” (Ex. 1003 at 2964) totaling approximately 4×10^8 T cells at week 5, when the composition was analyzed for immunophenotypes. See Petition at 37 (“After culture and expansion to clinically meaningful numbers at five weeks, Singh’s authors assessed CD45RO and CD45RA expression in its T-cell composition”); Ex. 1003 at Figure 4A (showing “Viable T-cell number” of approximately 8×10^8 at 35 days, i.e., 5 weeks) and Figure 4B (showing “Total CAR⁺” to be approximately 50% and similar percentages of CD4⁺CAR⁺ and CD8⁺CAR⁺ at 35 days). The amount of CAR T cells in the Singh-1 composition falls squarely within the ’308 patent’s disclosure of a “treatment-effective amount of cells in the composition,” which is “typically greater than 10^2 cells, and up to 10^6 , up to and **including 10^8 or 10^9 cells** and can be more than 10^{10} cells.” ’308 patent at 18:36-40. Singh-1 showed that its CAR T cell composition “were able to lyse CD19⁺ targets” with *in vitro* efficacy data. Ex.1003 at 2968-69, Figure 5. The Singh-1 reference indisputably states that the disclosed composition could be used in “a next-generation clinical trial,” i.e., therapeutically *in vivo*. Petition at 32-34; Ex.1003 at 2970-2971.

The Singh-1 disclosures are more than sufficient to enable a POSA to make and administer the Singh-1's CAR T composition to an animal or human. Under controlling precedent, enablement for anticipation does not require Singh-1 to demonstrate utility or efficacy with *in vivo* data or other teachings. Petitioner respectfully requests that the Board find that Singh-1 has satisfied the enablement requirement for purposes of anticipation.

II. SINGH-2 DOES NOT NEGATE SINGH-1'S CONCLUSION THAT ITS COMPOSITION HAD "CD4+ AND CD8+ CAR+ T CELLS [OF] CLINICALLY MEANINGFUL NUMBERS"

The Decision states that "even if the presumption of enablement applies to Singh-1, Patent Owner has provided sufficient evidence to rebut that presumption." Decision at 22. Specifically, the Board found that "Singh-2 demonstrates that IL-2 alone in the culture medium leads to predominant outgrowth of CAR⁺ CD4⁺ T cells" as compared to using IL-2 and IL-21 together in the culture medium. *Id.* at 24. The Board then concluded that Singh-1's culturing process would lead to an outgrowth of CD4⁺ CAR⁺ T cells and therefore "would *not* have exhibited any significant therapeutic efficacy." *Id.*, 24-25. There are several issues with this conclusion.

First, Petitioner cited as anticipatory the Singh-1 CAR T composition generated at week five of the culturing process, which had "CD4⁺ and CD8⁺ CAR⁺ T cells [in] clinically meaningful numbers" after five weeks of *ex vivo* expansion

and the immunophenotype characteristics within scope of claim 1 of the '308 patent. Petition at 21-22, 37. This CAR T composition did **not** have an outgrowth of CD4⁺ CAR⁺ T cells to the detriment of CD8⁺ CAR⁺ T cells. The percentage of CAR⁺ CD8⁺ T cells in this composition was 34% of the overall population and 42% of CD8⁺ T cells. Reply at 1, 4-5, citing Ex. 1003 at Figure 3B. This is drastically different from the outgrowth of CD4⁺ CAR⁺ T cells seen in one of Singh-2's compositions whereby there was CAR expression in only 1% of CD8⁺ T cells. Patent Owner never disputed that the compositions in Singh-1 and Singh-2 were different.

The Decision cites a portion of Singh-1 which states that an outgrowth of CD4⁺ T cells occurred "after ~8 weeks." Decision at 24. But this does not invalidate Singh-1's teaching of making a CAR T composition that was cultured for five weeks and had "CD4⁺ and CD8⁺ CAR⁺ T cells [in] clinically meaningful numbers," no detrimental outgrowth of CD4⁺ cells, and the immunophenotype characteristics within the scope of claim 1 of the '308 patent. The Petition and Dr. Bramson's Declaration (Ex. 1002, "Bramson") explained that this five-week CAR T composition was used for successful *in vitro* experiments and would be expected to be successful *in vivo* as well. Petition at 22 ("After CAR transduction and five weeks of ex vivo expansion"), 37 ("After culture and expansion to clinically meaningful numbers at five weeks, Singh's authors assessed CD45RO

and CD45RA expression in its T-cell composition”); Ex. 1002, ¶103 (“After CAR transduction and five weeks of ex vivo T-cell expansion, Singh’s authors analyzed the immunophenotypes of the resulting T-cell compositions”); *id.* ¶¶102-123.

That Singh-2 disclosed a different culturing process using IL-2 and IL-21 that resulted in 76% CAR⁺ expression for CD8⁺ cells does not indicate that the Singh-1’s 42% expression rate is somehow insufficient. Patent Owner has never argued that 42% is insufficient. Instead, Patent Owner has only ever argued that Singh-2’s other composition of 1% CAR⁺ expression for CD8⁺ cells is insufficient for *in vivo* efficacy. Sur-Reply at 9. But, as Petitioner noted in Reply, the Singh-1 composition that is anticipatory has 34% CAR⁺ expression for CD8⁺ T cells and 42% CAR⁺ expression for CD8⁺ T cells. Reply at 4. Nothing in the Singh-2 abstract suggests that such a composition would not be effective *in vivo*.

Second, the Singh-2 abstract lacks sufficient detail to conclude that its IL-2-only culturing process was the same as the Singh-1 culturing process. As discussed above, the end results were different, which strongly indicates that the culturing process was different. As Petitioner explained, Singh-2 was silent on numerous key parameters of its culturing process. Reply at 5. Even though there was some overlap of authorship, this does not mean that Singh-1 and Singh-2 used the exact same culturing process. Indeed, Petitioner showed that Singh-3, a post-priority-

date reference that Patent Owner tied to Singh-2, indicated that the culturing process for Singh-1 and Singh-2 were different. *Id.*

Third, the Singh-2 abstract never states that using IL-2 only in the culturing process would result in no *in vivo* efficacy. Indeed, Singh-2 has no efficacy data whatsoever. The abstract only states “that the addition of exogenous IL-21 favors the microenvironment to selectively propagate CAR CD8 T cells with ability to kill CD19⁺ tumor targets,” (Ex. 2003 at 1), but that is a far cry from suggesting that any prior results not using IL-21 would lack *in vivo* efficacy. The Decision was erroneous in finding that the Singh-2 abstract demonstrates that “the culturing process used in Singh-1 ‘would **not** have exhibited any significant therapeutic efficacy.’” Decision at 24-25. Indeed, the Singh-2 abstract contained no efficacy data whatsoever (*in vitro* or *in vivo*). In contrast, the Singh-1 article showed that its CAR T cell compositions “were able to lyse CD19⁺ targets” and reported *in vitro* efficacy results. Ex. 1003 at 2968-69, Figure 5. There is no logical reason to ignore Singh-1’s successful *in vitro* data because of Singh-2.

Fourth, even if Singh-2 is considered to contain negative results about the Singh-1 CAR T composition, it is legally improper to use such results in determining anticipation. As the Federal Circuit has explained, “negative results” even in the anticipatory reference itself do not impact the anticipation analysis. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005),

quoting *Bristol–Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). “[T]he question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis.” *Id.* at 1326. This is because, as discussed above, “proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation” and “anticipation does not require actual performance of suggestions in a disclosure.” *Id.*

For these reasons, Petitioner respectfully requests that the Board find that Singh-2 does not invalidate Singh-1’s teaching that its compositions had CD4⁺ and CD8⁺ CAR⁺ T cells in clinically meaningful numbers and therefore would have expected *in vivo* efficacy.

In sum, the Board should institute *Inter Partes Review* because Petitioner has shown a reasonable likelihood that Singh-1 is enabled for purposes of anticipation.

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Certificate of Service

I hereby certify, pursuant to 37 C.F.R. §§42.6 and 42.105, that a complete copy of the attached **Petitioners' Request for Rehearing**, is being served on the twenty-fifth day of October, the same day as the filing of the above-identified document in the United States Patent and Trademark Office/Patent Trial and Appeal Board, upon the patent owner by serving via electronic mail to the following:

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