UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/283,093	05/20/2014	ROBERT PYTELA	EPIT-016CON4	5026

93726 7590 09/26/2019

EPA - BOZICEVIC FIELD & FRANCIS LLP
BOZICEVIC, FIELD & FRANCIS
201 REDWOOD SHORES PARKWAY
SUITE 200
REDWOOD CITY, CA 94065

EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/26/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@bozpat.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT PYTELA, WEIMIN ZHU, YAOHUANG KE, QI QIAN, and HARRY C. AU[1]

Appeal 2019-001619
Application 14/283,093[2]
Technology Center 1600

Before TONI R. SCHEINER, DONALD E. ADAMS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The claims in this appeal are directed to a rabbit-derived immortal B-lymphocyte capable of fusing with a rabbit splenocyte. The Examiner rejected the claims under the doctrine of obviousness-type double-patenting. Pursuant to 35 U.S.C. § 134, Appellants appeal the Examiner's determination that the claims are unpatentable. We have jurisdiction for the appeal under 35 U.S.C. § 6(b). The Examiner's decision is AFFIRMED.

---

[1] The Appeal Brief ("Appeal Br." entered July 30, 2018) lists Epitomics, Inc., which is a subsidiary of Abcam, as the real-party-in-interest. Appeal Br. 3.

[2] "The '093 application."

STATEMENT OF THE CASE

The Examiner finally rejected the claims as follows:

Claims 16–21 on the ground of nonstatutory obviousness-type double patenting as obvious in view of 1) claims 1–12 of U.S. Patent No. 8,062,867 B2 (issued Nov. 22, 2011) ("the '867 patent"), 2) claims 1–6 of U.S. Patent No. 7,429,487 B2 (issued Sept. 30, 2008) ("the '487 patent"), and 3) claims 1–7 of U.S. Patent No. 8,367,408 B2 (Feb. 5, 2013) ("the '408 patent"). Ans. 4.

Claims 16–21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16–23 of co-pending Application No. 15/089,135 ("the '135 application").[3] Ans. 4.

Rejected claims

Claim 16, the only independent claim on appeal, is reproduced below:

> 16. A rabbit-derived immortal B-lymphocyte capable of fusing with a rabbit splenocytes [sic, splenocyte] to produce a hybrid cell that produces an immunoglobulin, wherein the rabbit-derived immortal B-lymphocyte fuses with rabbit splenocytes a rate of at least 40%.

Dependent claim 21 recites "wherein the rabbit-derived immortal B-lymphocyte fuses with rabbit splenocytes a rate of at least 64%."

U.S. Patent No. 8,062,867

Claim 1 of the '867 patent is reproduced below:

> 1. A method of making a hybrid cell that produces an antibody, comprising:

[3] This Application issued August 13, 2019 as US 10,377,814. Therefore, this rejection is no longer provisional.

> fusing a first cell that produces an antibody with a rabbit derived immortal B-lymphocyte, wherein immunoglobulin heavy chain (IgH) mRNA expression of said rabbit-derived immortal B-lymphocyte is not detectable by RT-PCR and said rabbit derived immortal B-lymphocyte does not detectably express IgH,
>
> thereby producing an [sic, a] hybrid cell that produces said antibody.

The claims of the ’867 patent are directed to making a hybrid cell that makes an antibody. The hybrid cell is made by fusing 1) a first cell that produces an antibody with 2) a rabbit derived immortal B-lymphocyte. The “rabbit derived immortal B-lymphocyte” of the ’867 patent corresponds to the “rabbit derived immortal B-lymphocyte” of rejected claim 16. Claim 1 of the ’867 patent does not recite a specific fusion rate for the immortal B-lymphocyte as does claim 16 of the ’093 application. Claim 1 also requires the cells not to produce immunoglobulin heavy chains, which is not a requirement of rejected claim 16. The issue in the rejection is whether the claimed fusion rate “of at least 40%” recited in claim 16 of the ’093 application, in cells which are not limited as to heavy chain immunoglobulin expression, would have been obvious to one of ordinary skill in the art.

As mentioned above, the immortal B-lymphocyte of rejected claim 16 is not required by the claim to *not* produce a heavy chain as in claim 1 of the ’867 patent. However, the claim is unlimited as to heavy chain expression, and thus the claim encompasses cells which do *not* produce heavy immunoglobulin chains and therefore the patented ’867 claim falls with the broader scope of claim 16 with respect to this limitation.

Appellants argue that “a fusion rate ‘of at least 40%’ cannot necessarily flow from the claims of” the ’867 patent “because there are other

examples of rabbit derived immortal B-lymphocytes that have a much lower fusion rate." Appeal Br. 5. As evidence of this, Appellants cite the Knight patent (U.S. Pat. No, 5,675,063, issued Oct. 7, 1997) which Appellants state describes "a rabbit-derived B-lymphocyte capable of fusing with rabbit splenocytes to produce a hybrid cell, where the rabbit-derived B-lymphocyte has a fusion rate of less than 1%." *Id.*

This argument is not persuasive.

The Examiner stated that one of ordinary skill in the art would have been motivated to elect a B-lymphocyte with a specific fusion rate, including the claimed fusion rate of at least 40%. Ans. 9.

While it may be true that lower fusion rates are known in the prior art, as established by Knight, Appellants did not provide a reason why it would not have been obvious to obtain a cell with the claimed fusion rate of at least 40% using routine and conventional screening. The rejection is not based on inherency as argued by Appellants (Appeal Br. 5), but rather on the obviousness of obtaining cells with the desired fusion rate (Ans. 9). As held in *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990):

> [The] law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims…in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

Thus, Appellants have the burden of showing that claimed fusion rate of rejected claim 16 is critical and unexpected relative to claim 1 of the '867 patent which is unlimited as to the fusion rate. This burden was not met.

Appellants also argue that "there is no biological connection between heavy chain expression and high fusion rate. As such, there should be no

obviousness between the present claims and the claims of the prior patents." Reply Br. 2. However, the claims of the '093 application are not limited as to the status of the heavy chain expression. Thus, a "connection" between immunoglobulin expression and fusion rate is not required by claim 16.

Dependent claim 8 of the '867 patent further recites "wherein said immortal B-lymphocyte has a hybridization frequency of at least 80%." The "hybridization frequency" of at least 80% of claim 8 of the '867 patent falls within the broader scope of at least 40% of rejected claim 16 and at least 64% recited in rejected dependent claim 21 and thus *meets* the claimed limitation. It is well established that, when there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, as here, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004). *See* also arguments above citing *Woodruff*. Thus, claim 16 ("at least 40%") and claim 21 ("at least 64%") are also obvious in view of claim 8 of the '867 patent.

For the foregoing reasons, the obviousness-type double-patenting rejection of claims 16 and 21 over the claims of the '867 patent is affirmed. Claims 17–20 were not separately argued and therefore fall with claim 16. 37 C.F.R. § 41.37(c)(1)(iv).

U.S. Patent No. 7,429,487

Claim 1 of the '487 patent is reproduced below:

> 1. A rabbit-derived immortal B-lymphocyte capable of fusing with a rabbit splenocyte to produce a hybrid cell that produces an immunoglobulin, wherein immunoglobulin heavy chain mRNA expression of said rabbit derived immortal B-

> lymphocyte is not detectable by RT-PCR and said rabbit-derived immortal B-lymphocyte does not detectably express immunoglobulin heavy chain.

Claim 1 of the ’487 patent is directed to “[a] rabbit-derived immortal B-lymphocyte capable of fusing with a rabbit splenocyte to produce a hybrid cell that produces an immunoglobulin, wherein immunoglobulin heavy chain mRNA expression” is not detectable by RT-PCR and the heavy chain is not expressed by the B-lymphocyte. Claim 3, which depends from claim 1, further recites “wherein said immortal B-lymphocyte has a hybridization frequency of at least 80%.”

Claim 1 of the ’487 patent does not recite a specific fusion rate for the immortal B-lymphocyte. Thus, the issue in the rejection is whether the claimed cells, which are unlimited as to immunoglobulin heavy chain expression, and which recite a fusion rate “of at least 40%”, would have been obvious to one of ordinary skill in the art in view of claims 1 and 3 of the ’487 patent.

The immortal B-lymphocyte of rejected claim 16 is not required by the claim to *not* produce a heavy chain as in claim 1 of the ’487 patent. However, claim 16 encompasses cells which do not produce heavy immunoglobulin chains and therefore the patented ’487 claim falls with the broader scope of claim 16 with respect to this limitation.

Rejected claim 16 requires the fusion rate to be at least 40%. Claim 1 of the ’487 patent is not limited to a specific fusion rate. The Examiner stated that one of ordinary skill in the art would have been motivated to select a B-lymphocyte with a specific fusion rate, including the claimed fusion rate. Ans. 9.

Appellants contend that there are numerous examples of cells with lower fusion rates, citing Knight as an example. Appeal Br. 5.

This argument is not persuasive. As discussed above for the '867 patent, Appellants did not provide a reason why it would not have been obvious to obtain a cell with the claimed fusion rate using routine and conventional screening. As held in *In re Woodruff*, 919 F.2d at 1578:

> [The] law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims…in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

Thus, Appellants have the burden of showing that claimed fusion frequency of rejected claim 16 is critical and unexpected relative to claim 1 of the '487 patent. This burden was not met.

Claim 3 of the '487 patent recites hybridization frequency of at least 80% which overlaps and is encompassed by the 40% value of claim 16 and the 64% value of claim 21 of the '093 application. Thus, claims 16 and 21 are also obvious in view of claim 8 of the '487 patent for the same reasons set forth above in the discussion of the '867 patent.

For the foregoing reasons, the obviousness-type double-patenting rejection of claims 16 and 21 over the claims of the '487 patent is affirmed. Claims 17–20 were not separately argued and therefore fall with claims 16 and 21. 37 C.F.R. § 41.37(c)(1)(iv).

U.S. Patent No. 8,367,408

Independent claim 1 of the '408 patent is reproduced below:

> 1. A hybrid cell made by fusing a rabbit spleen cell with a myeloma cell, wherein:
>
> said rabbit spleen cell produces an antibody;
>
> said myeloma cell does not detectably express rabbit IgH and immunoglobulin heavy chain (IgE) mRNA expression of said myeloma cell is not detectable by RT-PCR; and
>
> said hybrid cell produces said antibody.

Claim 1 of the ’408 patent comprises a “myeloma cell” which “does not detectably express rabbit IgH and immunoglobulin heavy chain (IgE) mRNA expression of said myeloma cell is not detectable by RT-PCR.” The issue is whether the claimed “rabbit-derived immortal B-lymphocyte” that “fuses with rabbit splenocytes a rate of at least 40%” of the ’093 application would have been obvious to one of ordinary skill in view of claim 1 of the ’408 patent.

From the description in Appellants’ Specification that the disclosed rabbit-derived immortal B-lymphocytes can be the myeloma-like 240E-1 cells, we find that the claimed “rabbit-derived immortal B-lymphocyte” can be a myeloma cell as in claim 1 of the ’408 patent. Spec. 1:29–Spec. 2:10; Spec. 14:9–10. The immortal B-lymphocyte of rejected claim 16 is not required by the claim to *not* produce a heavy chain as in claim 1 of the ’4 08 patent. The heavy immunoglobulin chain expression limitation of claim 1 of the ’408 patent falls within the scope of rejected claim 16 because claim 16 is broader and thus a cell with this immunoglobulin characteristic meets the claimed cell.

Claim 1 of the ’408 patent does not require a fusion rate of 40% as recited in rejected claim 16. The Examiner stated that one of ordinary skill in the art would have been motivated to select a B-lymphocyte with a specific fusion rate, including the claimed fusion rate. Ans. 9.

Appellants contend that there are numerous examples of cells with lower fusion rates, citing Knight as an example. Appeal Br. 5. Appellants also argue that "there is no biological connection between heavy chain expression and high fusion rate. As such, there should be no obviousness between the present claims and the claims of the prior patents." Reply Br. 3.

This argument is not persuasive for the same reasons discussed above. Appellants did not provide a reason why it would not have been obvious to have obtained a cell with the claimed fusion rate using routine and conventional screening nor establish that the claimed fusion rate is critical.

For the foregoing reasons, the obviousness-type double-patenting rejection of claim 16 over the claims of the '487 patent is affirmed. Claims 17–21 were not separately argued and therefore fall with claim 16. 37 C.F.R. § 41.37(c)(1)(iv).

Application No. 15/089,135

The claims of the '135 application received an issue notification on July 24, 2019.

Claim 16 of the '135 application is reproduced below:

> 16. A hybrid cell produced by fusing: i. an antibody-producing cell of a rabbit with ii. a rabbit-derived immortal B-lymphocyte, wherein immunoglobulin heavy chain (IgH) mRNA expression of the rabbit-derived immortal B-lymphocyte is not detectable by RT-PCR and said rabbit derived immortal B-lymphocyte does not detectably express immunoglobulin heavy chain.

Claim 16 of the '135 application comprises a "rabbit-derived immortal B-lymphocyte, wherein immunoglobulin heavy chain (IgH) mRNA expression of the rabbit-derived immortal B-lymphocyte is not detectable by RT-PCR and said rabbit derived immortal B-lymphocyte does

not detectably express immunoglobulin heavy chain." Claim 16 of the '093 application is obvious view of the '135 application claims for the same reasons the claim is obvious over the claims of the '867 patent, the '487 patent, and the '408 patent.

Claims 17–21 were not separately argued and therefore fall with claim 16. 37 C.F.R. § 41.37(c)(1)(iv).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED