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| EXAMINER | |
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| ROARK, JESSICA HOPE | |

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* NICOLAS BAURIN, CHRISTIAN BEIL, CARSTEN CORVEY, CHRISTIAN LANGE, DANXI LI, VINCENT MIKOL, ANKE STEINMETZ, and ERCOLE RAO

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Appeal 2024-002920
Application 17/135,529
Technology Center 1600

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Before ERIC B. GRIMES, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges.*

TOWNSEND, *Administrative Patent Judge.*

## DECISION ON APPEAL

## STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims directed to dual variable region antibody-like binding proteins having cross-over binding region orientation for nonstatutory double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as SANOFI. (Appeal Br. 3.)

## CLAIMED SUBJECT MATTER

Claims 1–18 are on appeal. Claim 1, reproduced below, illustrates the claimed subject matter:

> 1. An antibody-like binding protein comprising two polypeptide chains that form two antigen binding sites, wherein a first polypeptide chain comprises the structure $V_{L1}$-$L_1$-$V_{L2}$-$L_2$-$C_L$, and a second polypeptide chain comprises the structure $V_{H2}$-$L_3$-$V_{H1}$-$L_4$-$C_{H1}$;
>
> wherein:
>
> (a) $V_{L1}$ is derived from a $V_H$ of a first immunoglobulin heavy chain variable domain, $V_{L2}$ is derived from a $V_H$ of a second immunoglobulin heavy chain variable domain, $V_{H2}$ is derived from a $V_L$ of a second immunoglobulin light chain variable domain, and $V_{H1}$ is derived from a $V_L$ of a first immunoglobulin light chain variable domain;
>
> wherein $V_{L1}$ and $V_{H1}$ associate to form a first antigen binding site, and $V_{L2}$ and $V_{H2}$ associate to form a second antigen binding site;
>
> (b) $C_L$ is an immunoglobulin light chain constant domain;
>
> (c) $C_{H1}$ is the immunoglobulin $C_{H1}$ heavy chain constant domain; and
>
> (d) $L_1$, $L_2$, $L_3$, and $L_4$ are amino acid linkers;
>
> wherein $L_1$ is 3 to 12 amino acid residues in length, $L_2$ is 3 to 14 amino acid residues in length, $L_3$ is 1 to 8 amino acid residues in length, and $L_4$ is 1 to 3 amino acid residues in length; or
>
> $L_1$ is 1 to 3 amino acid residues in length, $L_2$ is 1 to 4 amino acid residues in length, $L_3$ is 2 to 15 amino acid residues in length, and $L_4$ is 2 to 15 amino acid residues in length; and
>
> wherein the first and second polypeptides form a cross-over light chain-heavy chain pair.

## REFERENCES

The Examiner relies on the following references to reject the claims:

| Name | Reference | Date |
|---|---|---|
| Yang | US 10,882,922 B2 | Jan. 5, 2021 |
| Yang | US 11,192,960 B2 | Dec. 7, 2021 |
| Wu | US 11,186,649 B2 | Nov. 30, 2021 |
| Wu | US 11,530,268 B2 | Dec. 20, 2022 |
| Beil | US 11,613,576 B2 | Mar. 28, 2023 |
| Klein | US 2009/0162359 A1 | June 25, 2009 |
| Beil | US Patent Application 18/183,107 | |

## REJECTIONS

The Examiner maintains the following rejections:

Claims 1–18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–39 of U.S. Patent No. 10,882,922 in view of Klein.

Claims 1–4 and 6–18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–41 of U.S. Patent No. 11,186,649 in view of Klein.

Claims 1–4 and 6–18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–34 of U.S. Patent No. 11,530,268 in view of Klein.

Claims 1–4 and 6–18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–7, 9–11, and 13–29 of U.S. Patent No. 11,613,576 in view of Klein.

Claims 1–18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–30 of U.S. Patent No. 11,192,960 in view of Klein.

Claims 1–18 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 163–167, 223–230, and 232–244 of copending Application No. 18/183,107 in view of Klein.

## DISCUSSION

The Examiner's nonstatutory double patenting rejections and Appellant's argument of Examiner error is the same for all grounds. (*See* Final Action 6, 8–12; *see generally* Appeal Brief.) We focus our discussion below on the Examiner's nonstatutory double patenting rejection based on the '922 patent claims as the applied reference.

The Examiner recognizes that the '922 patent does not have identical claims to those on appeal, but contends that they are not patentably distinct because the claims of that patent are directed to a trispecific construct that contains the "instantly recited bispecific 'cross-over' constructs and linkers . . . except for the 'swapping' of the VL and VH domains." (Final Action 6.) The Examiner finds, however, that "Klein teaches that swapping of domains is not only tolerated in multiple constructs, but can be used to facilitate correct chain association and reduce unwanted biproducts [sic]." (*Id.* at 4 (citing Klein Figure 2), 6.) The Examiner concludes that

> the ordinary artisan would have considered an antigen-binding molecule in which the VL are each "derived from" the VH of the parent antibodies and the VH are each "derived from" the VL of the parent antibodies to be an obvious alternate embodiment to that recited in the claims of the '917.

(*Id.* at 4, 7 ("The claimed constructs are obvious alternatives to those recited in the claims of the '922, essentially for the reasons noted above regarding the claims of the '917 in view of the teachings of Klein regarding the swapability of VH and VL domains.").)

Appellant argues that the Examiner's rejection is in error because the '922 patent does not qualify as a reference for purposes of nonstatutory double patenting because (a) it has a later filing date compared to the application at issue and (b) it expires later than any patent claims that would issue from the application at issue. (Appeal Br. 7.) Regarding filing dates, Appellant explains that the instant claims have a filing date of March 28, 2012, corresponding to the filing date of U.S. Application No. 13/433,033, whereas the '922 patent claims have a filing date of April 13, 2017, corresponding to the filing date of U.S. Application No. 15/487, 243. (*Id.* at 9.) Regarding expiration dates, Appellant explains that "it is indisputable that, in view of the terminal disclaimers filed herewith (i.e., over US Pat Nos. 9,221,917 and 9,181,349) . . . any patent issuing from the instant application cannot extend beyond March 28, 2032." (*Id.* at 10–11.) Appellant explains that the '922 patent has a 20-year statutory term that ends on April 13, 2037 and received 70 days of PTA.[2] (*Id.*)[3]

Appellant urges that the Federal Circuit has noted that "claims 'are entitled to their full term, including . . . duly granted PTA, unless they are

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[2] PTA stands for patent term adjustment for, *inter alia*, any delay in prosecution due to the failure of the U.S. Patent and Trademark Office to timely examine the application, and is codified under 35 U.S.C. § 154(b)(1)(A)–(B). *Allergan USA, Inc. v. MSN Labs. Private LTD.*, 111 F.4th 1358, 1367 (Fed. Cir. 2024).

[3] The filing dates of the '649 patent, the '268 patent, the '576 patent, the '960 patent, and the copending '107 application all post-date the filing of the application on appeal and all will expire later than any patent issuing from the application on appeal. (*See* Appeal Br. 20 ('649 patent application filed October 9, 2018); *id.* at 26 ('268 patent application filed October 8, 2019), *id.* at 32 ('576 patent application filed April 8, 2020); *id.* at 38 ('960 patent application filed April 13, 2017); *id.* at 43 (the '107 patent application filed April 8, 2020).)

found to be later-filed obvious variations of **earlier-filed** . . . claims." (Appeal Br. 7 (quoting *In re Cellect, LLC*, 81 F.4th 1216, 1230 (Fed. Cir. 2023)).) Additionally, Appellant notes that the Federal Circuit has held "for patents to which the URAA[4] applies (e.g., any patent issuing from the instant application) – expiration dates are the controlling factor for nonstatutory double patenting." (*Id.* at 9 (citing *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014).)

We agree with Appellant that the claims of the '922 patent cannot serve as reference claims against the claims on appeal for purposes of nonstatutory double patenting.

The '529 patent application was filed on December 28, 2020 but claims priority through a chain of continuations to a provisional application filed March 28, 2011. The '922 patent was filed April 13, 2017 and claims priority to a number of provisional applications, the earliest of which was filed April 13, 2016. Appellant explains that the '922 patent has a 20-year statutory term that ends on April 13, 2037 and received 70 days of PTA.[5] As

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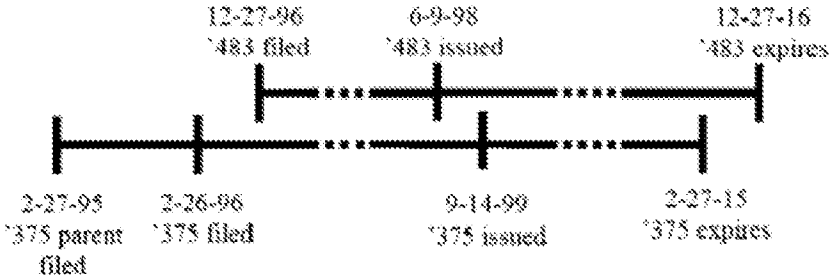
[4] URAA stands for Uruguay Round Agreements Act, Publ. L. No. 103-465, § 532(a) (1994). *See Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1211 (Fed. Cir. 2014).

[5] The '649 patent was filed October 9, 2018 and claims priority to several provisional applications, the earliest of which was filed October 10, 2017. The '268 patent was filed October 8, 2019 and claims priority to a number of provisional applications, the earliest of which was filed April 9, 2019. The '576 patent was filed April 8, 2020 and claims priority to a number of provisional applications, the earliest of which was filed April 9, 2019. The '960 patent was filed November 16, 2020 as a continuation of an application filed April 13, 2017 and claims priority to a number of provisional applications, the earliest of which was filed April 13, 2016. The '107 patent application was filed March 13, 2023 as a continuation of an application

Appellant also explained, in light of the Terminal Disclaimers that have been filed in the application on appeal, any patent claims issuing from the application on appeal will have a term that cannot extend beyond March 28, 2032, which is well before the expiration of the '922 patent claims.

The purpose of the nonstatutory double patenting doctrine "is to prevent patentees from obtaining a *second* patent on a patentably indistinct invention to effectively extend the life of a *first* patent to that subject matter." *Allergan USA, Inc. v. MSN Labs. Private LTD.*, 111 F.4th 1358, 1369 (Fed. Cir. 2024). Our reviewing court has addressed what is a first and a second patent in terms of nonstatutory double patenting in a number of cases. In *Gilead*, the Federal Circuit explained that a first-filed application (the '375 patent) that issued as a patent, but had an earlier patent term expiration date than a second later-filed patent application (the '483 patent) that issued prior to the first-filed application could qualify as a double patenting reference, *see* timeline below. 753 F.3d at 1217.




*Gilead*, 753 F.3d at 1210. The above time-line shows that a continuation application to which the '375 patent claims priority was filed in February

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filed April 8, 2020 and claims priority to a number of provisional applications, the earliest of which was filed April 9, 2019. The 20-year statutory period for these patents will all expire several years after March 28, 2032, the latest expiration date for any patent to issue from the application on appeal.

1995, that the '375 patent issued in September 1999 and expires February 2015, whereas the second filed patent, the '483 patent, was filed December 1996, issued before the reference patent in June 1998, but expires after the reference patent in December 2016. The problem the court found was that because the claims of the '483 patent were filed after, claimed a later priority date than, and expired after the reference claims, the '483 patent claims resulted in an unwarranted extension of patent term for an invention that had already been the subject of an earlier-filed, earlier-expiring claim, i.e., the '375 patent. *Allergan*, 111 F.4th at 1370.

A similar factual situation was presented in *Abbvie v. Mathilda & Terrence Kennedy Institute*, 764 F. 3d 1366 (Fed. Cir. 2014), the only difference being the earlier filed reference patent also issued earlier than the second filed, later expiring patent. 764 F.3d at 1369–1370. The court held that the difference in expiration dates was sufficient for the earlier effectively filed application, with an earlier expiration date than the second patent, to be a reference patent against the second patent. *Id.* at 1374.

Notably, in both of the foregoing cases, the reference patent claims had an earlier filing date than the patent against which they were applied in the nonstatutory double patenting analysis and an earlier expiration date. In contrast, here, the Examiner is applying, as the reference claims for the nonstatutory double patenting rejection, claims from a second, later-filed application that was earlier-issued, but would be later expiring than claims that would issue from the application on appeal before us. We believe that difference is important and the facts here compel a different conclusion than in *Gilead* and *Abbvie*.

In *Allergan*, the court held that claims to the first patent ever to be filed covering a particular drug compound are not subject to nonstatutory double patenting over claims issued in a subsequently filed patent that shares a priority date with the first patent, even where those claims would expire later than the subsequently filed patent. *Allergan*, 111 F.4th at 1371. The court explained that is so because the first filed patent does not extend or prolong the monopoly beyond the period allowed by law; put differently it is not a "*second*, later expiring patent for the same invention." *Id.* (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894), and *Abbvie*, 764 F.3d at 1373). The *Allergan* court noted that "[a]s the first-filed, first-issued patent in its family, it is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants." *Id.*

While the facts of *Allergan* are somewhat different than here because the '922 patent and the application before us do not share a priority date or even stem from the same application family, we find the reasoning compelling. The application at issue here was filed before the application leading to the '922 patent, and was published well before the earliest effective filing date of the '922 patent. (Appeal Br 15–16.) The Examiner allowed the claims of the '922 patent over this publication, thus determining that the '922 claims are not obvious from that disclosure. (*Id.* at 16; *see also* Ans. 12 ("It is acknowledged that the claims of the later-filed now issued patents were non-obvious over the instant disclosure and could not have been presented in the instant application.").) In other words, the claims at issue would be a first patent to cover the antibody-like binding protein comprising two polypeptide chains that form two antigen binding sites, wherein a first polypeptide chain comprises the structure $V_{L1}$-$L_1$-$V_{L2}$-$L_2$-$C_L$,

and a second polypeptide chain comprises the structure $V_{H2}$-$L_3$-$V_{H1}$-$L_4$-$C_{H1}$ as claimed. It is not a second, later expiring patent for the same invention as the '922 patent, and as such does not extend a period of exclusivity on the claimed subject matter. Because we conclude that the '922 patent claims cannot serve as reference claims against the claims on appeal, we reverse the Examiner's rejection of claims 1–18 for nonstatutory double patenting as being unpatentable over claims 1–39 of the '922 patent in view of Klein.[6]

For the reasons discussed, we also conclude that the claims of the '649 patent, the '268 patent, the '576 patent, the '960 patent, and the '107 patent application also cannot serve as reference claims against the claims on appeal. Thus, we reverse the Examiner's rejection of:

> Claims 1–4 and 6–18 on the ground of nonstatutory double patenting as being unpatentable over claims 1–41 of U.S. Patent No. 11,186,649 in view of Klein,
>
> Claims 1–4 and 6–18 on the ground of nonstatutory double patenting as being unpatentable over claims 1–34 of U.S. Patent No. 11,530,268 in view of Klein,
>
> Claims 1–4 and 6–18 on the ground of nonstatutory double patenting as being unpatentable over claims 1–7, 9–11, and 13–29 of U.S. Patent No. 11,613,576 in view of Klein,

[6] The Examiner's arguments regarding a need to file a terminal disclaimer because of a risk of separate ownership between the claims of the '922 patent and the claims on appeal (Final Action 7–8) is immaterial where the '922 patent is not a proper nonstatutory double patenting reference. *See In re Cellect*, 81 F.4th at 1226 (noting that a terminal disclaimer "may be filed to *overcome* a [nonstatutory double patenting] rejection").

Claims 1–18 on the ground of nonstatutory double patenting as being unpatentable over claims 1–30 of U.S. Patent No. 11,192,960 in view of Klein, and

Claims 1–18 provisionally on the ground of nonstatutory double patenting as being unpatentable over claims 163–167, 223–230, and 232–244 of copending Application No. 18/183,107 in view of Klein.

DECISION SUMMARY

The following table summarizes our decision:

| **Claim(s) Rejected** | **35 U.S.C. §** | **Reference(s)/ Basis** | **Affirmed** | **Reversed** |
|---|---|---|---|---|
| 1–18 | | Nonstatutory Double Patenting: US Patent 10,882,922, Klein | | 1–18 |
| 1–4, 6–18 | | Nonstatutory Double Patenting: US Patent 11,186,649, Klein | | 1–4, 6–18 |
| 1–4, 6–18 | | Nonstatutory Double Patenting: US Patent 11,530,268, Klein | | 1–4, 6–18 |
| 1–4, 6–18 | | Nonstatutory Double Patenting: US Patent 11,613,576, Klein | | 1–4, 6–18 |
| 1–18 | | Nonstatutory Double Patenting: US Patent 11,192,960, Klein | | 1–18 |
| 1–18 | | Provisional Nonstatutory Double Patenting: US Patent Application 18/183,107, Klein | | 1–18 |
| **Overall Outcome** | | | | 1–18 |

REVERSED