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The Appeals Review Panel

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Overview

- On July 24, 2023, the United States Patent and Trademark Office (USPTO or Office) established the Appeals Review Panel (ARP).
- The ARP may be convened by the Director *sua sponte* to review decisions of the Patent Trial and Appeal Board (PTAB or Board) in ex parte appeals, re-examination appeals, and reissue appeals.

Overview

- The Appeals Review Panel, coupled with the Director Review process (including the option to delegate review of a Board decision to a Delegated Rehearing Panel), replaced the Precedential Opinion Panel process.
- The Precedential Opinion Panel (POP) was established in 2018 and was a body within the Patent Trial and Appeal Board (PTAB) that addresses issues of significant importance or that require clarification in patent law.

Precedential Opinion Panel Process

- The Precedential Opinion Panel typically included the Director, the Commissioner for Patents, and the Chief Judge of the PTAB.
- The Precedential Opinion Panel served two primary functions:

(1) it may be convened to rehear matters in pending trials and appeals, for example on issues of exceptional importance; and

(2) it may assist the Director in determining whether a decision previously issued by the PTAB should be designated as precedential or informative.

Precedential Opinion Panel Process

- The Precedential Opinion Panel Process heard a total of 376 cases between its inception in 2018 and its retirement in 2023
- Approximately 50,200 appeals were filed to the PTAB during this timeframe.
- Therefore, slightly less than 1% of all appealed cases were reviewed by the Precedential Opinion Panel.

Precedential Opinion Panel Process

- Once the POP reaches a decision in a given case, that decision may either be designated by the POP as “precedential”, “informative”, or “routine.”
- Before the creation of the POP, by default, every PTAB decision was designated as a “routine” decision unless otherwise specified.
- “Routine” decisions are binding in the case in which they are made, but are not otherwise binding authority. Now, every PTAB decision, other than a precedential decision by a POP, is a routine decision until it is designated as precedential or informative.
- A “precedential” PTAB decision is binding on future PTAB panels considering similar facts or issues, unless and until the decision is superseded by later binding authority.
- An “informative” PTAB decision is not binding, but articulates the PTAB’s recommended approach to certain recurring issues; setting forth “norms” that should be followed in most cases.

Appeals Review Panel

- The USPTO introduced the new Appeals Review Panel on July 24, 2023, to replace the Precedential Opinion Panel (POP)
- The Appeals Review Panel may, convene *sua sponte* to review a decision in an *ex parte* appeal, reexamination appeal, or reissue appeal, and the appeal will be repaneled to the ARP.
- Requests for ARP review will not be accepted or considered. Only the director can initiate a review.
  - To have the Precedential Opinion Panel review a case, either the PTAB would refer the case to the POP, or a party in the case could request that the PTAB refer the case to the POP.
  - ARP does not have a similar mechanism to request review at this time.

Appeals Review Panel

- Appeals at the Board shall be heard by at least 3 members of the Board, who shall be designated by the Director. See 35 U.S.C. § 6(c). Accordingly, the ARP shall consist of three members.
- The ARP is selected by the Director impartially and, by default, consists of the Director, the Commissioner for Patents, and the Chief Judge of the Patent Trial and Appeal Board (same composition as the POP).

Timing of the Appeals Review Panel

- The ARP aims to issue decisions as soon as possible and typically within three months of the grant of ARP review.
- An ARP review can take less time than an average POP review process in theory because the PTAB does not have to refer the case to the director or have a party in the case request that the PTAB refer the case to the director.

Effects of ARP Decision

- ARP review decisions are, by default, routine decisions as set forth in Standard Operating Procedure 2, Revision 11 (SOP 2).
- Routine ARP decisions may be nominated after issuance for precedential or informative designation, and such nominations will follow the procedure set forth in SOP 2.
- Stakeholders and the public may submit nominations for precedential or informative designation using the PTAB Decision Nomination web form, or by sending an email to PTAB_Decision_Nomination@uspto.gov.

Effects of ARP Decision

- "Routine" decisions are binding in the case in which they are made, but are not otherwise binding authority. Now, every PTAB decision, other than a precedential decision by a POP, is a routine decision until it is designated as precedential or informative.
- A "precedential" decision establishes binding authority concerning major policy or procedural issues, or other issues of exceptional importance, including constitutional questions, important issues regarding statutes, rules, and regulations, important issues regarding case law, or issues of broad applicability to the Board.
- An "informative" PTAB decision provides Board norms on recurring issues, guidance on issues of first impression to the Board, guidance on Board rules and practices, and guidance on issues that may develop through analysis of recurring issues in many cases.

Review of an ARP Decision

- An appellant may not request rehearing of ARP decisions.
- ARP decisions are appealable to the United States Court of Appeals for the Federal Circuit or reviewable by filing a civil action against the Director in the United States District Court for the Eastern District of Virginia using the same procedures for appealing or seeking remedy by civil action of other Board appeal decisions.
- An order by the Director delegating a decision to the ARP is treated like a timely request for rehearing for the purposes of 37 C.F.R. § 90.3(b) and, therefore, resets the time for appeal or civil action (where available) to no later than sixty-three (63) days after final resolution of the ARP process.

Status of the ARP

- As of November 2024, the ARP has not considered any reexamination appeals or reissue appeals.
- The ARP has considered and issued a decision in one *Ex Parte* Appeal case, *Ex parte Chamberlain*, 2022-001944.
- Presumably more cases are being currently Examiner by the ARP, however, considering the ARP aims to issue decisions as soon as possible and typically within three months of the grant of ARP review, it appears that close to no cases are being reviewed by the ARP at this time.

Status of the ARP

- Since going into effect on July 24, 2023 (over a year ago), the ARP has only issued one decision.
- In contrast, the POP (which the ARP replaced) averaged roughly 75 decisions per year between its inception in 2018 and retirement in 2023.
- Could the ARP be scaling up? Possibly, but only issuing one decision in an entire year makes this unlikely.
- The ARP removes a mechanism for the PTAB and parties to request review by the Director. Therefore, the ARP will only intervene in cases in which the Director deems fit.

Ex parte Chamberlain, 2022-001944

The Initial Appeal by the Applicant

- The Examiner rejected claims 8 and 9 under the doctrine of obviousness-type double-patenting.
- Claims 8 and 9 were rejected under the judicially created doctrine of obviousness type double patenting as obvious in view of claims 1-5 of U.S. Patent No. 10,336,818 ("the '818 patent") and Schwaeble et al. (U.S. Pat. App. Pub. 2006/0018896 Al, published Jan. 26, 2006) ("Schwaeble").

Ex parte Chamberlain, 2022-001944

- Claims 8 and 9 were rejected under the judicially created doctrine of obviousness-type double patenting as obvious in view of claim I of U.S. Patent No. 8,546,543 ("the '543 patent") and Schwaeble.
- Claim 8 is directed to a method of treating a patient with an anti-C5 antibody having a Fe domain. The claim is in "Jepson" form. A Jepson claim has a preamble that recites what is "conventional or known," following by a recitation "which the applicant considers as the new or improved portion." 37 C.F.R. § l.75(e).
- Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner's decision to reject the claims.

Ex parte Chamberlain, 2022-001944

Claim 8 is reproduced below:

8. In a method of treating a patient by administering an anti-C5 antibody with an Fe domain, the improvement comprising said Fe domain comprising amino acid substitutions M428L/N434S as compared to a human F c polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Ex parte Chamberlain, 2022-001944

Claim 9 is reproduced below:

9. A method of treating a patient by administering an anti-C5 antibody comprising: a) means for binding human C5 protein; and b) an F c domain comprising amino acid substitutions M428L/N434S as compared to a human Fe polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Ex parte Chamberlain, 2022-001944

- The Fc region of antibodies is critical for their interaction with Fc receptors and other components of the immune system, such as complement proteins. By making changes to the Fc region, researchers can improve an antibody's stability and performance.
- The M428L/N434S substitutions are part of a well-established strategy to improve antibody half-life by enhancing FcRn binding. This modification has been used in various therapeutic antibodies to increase their efficacy and reduce the need for frequent dosing.

Ex parte Chamberlain, 2022-001944

Claim 8

- Claim 8 is directed to a method of "treating a patient" with "an antiC5 antibody with an F c domain," where the improvement is in the F c domain "comprising amino acid substitutions M428L/N434S as compared to a human Fe polypeptide.“
- The PTAB interprets an "anti-C5 antibody" to be an antibody that binds to the C5 complement protein in the normal way that antibodies bind to their cognate antigens (through the variable region of the antibody depicted in the image above).
- The claimed method of treating a patient is broad, comprising a broad genus of antibodies, treatment indications, and patients. In contrast, there is only one species disclosed in the Specification.

Ex parte Chamberlain, 2022-001944

- Therefore, the PTAB added a new ground of rejection, stating that claim 8 is rejected under 35 U.S.C. § 112(a) as lacking a written description of the claimed anti-C5 antibody.
- The PTAB finds that the disclosure of only a single antibody species is insufficient to provide a description of the broadly claimed genus of antibodies which are used to treat a patient for an unspecified disease or condition.

Ex parte Chamberlain, 2022-001944

Claim 9

- Claim 9 recites administering "an anti-C5 antibody" comprising a "means for binding human C5 protein.“
- The first question is whether the specific element in the claim should be construed as a "means-plus-function.
- If the means recited in the claim has a definite structure by itself, then pre-AIA § 112, 6th paragraph or § 112(f) is not applicable. However, the PTAB holds that there is no evidence of record that the claimed "means for binding human C5" would be "understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.“
- Therefore, 35 U.S.C. § 112(f) is applicable.

Ex parte Chamberlain, 2022-001944

- Having found that the "means for binding human C5 protein" is subject to the application of § 112(f), the PTAB next determines the function of the means and whether the specification discloses sufficient structure that corresponds to the claimed function.
- The function of the recited "means" is recited as "for binding the human C5 protein." Thus, the function of the "means" is to bind human C5.
- However, the PTAB holds that the specification does not disclose sufficient structure corresponding to the claimed function.
- Accordingly, the PTAB finds that claim 9 lacks adequate written description under 35 U.S.C. § 112(a) and is further indefinite under 35 U.S.C. § 112(b), as it is unclear what “treating a patient” means.

Ex parte Chamberlain, 2022-001944

- Regarding the obvious-double type patenting, the Examiner held that the '818 patent claims are directed to host cells, expression vectors, and nucleic acids for making the same Fc variant recited in instant claims 8 and 9.
- In addition, the Examiner held that the '543 patent claim is directed to an antibody conjugated to a drug ["ADC"], where the antibody comprises the same F c variant which is claimed.
- Each of the claims is rejected by the Examiner as obvious in combination with Schwaeble.
- The Examiner found that Schwaeble discloses anti-C5 antibodies for various utilities, including treatment ("therapeutics"). Final Act. 17. Prior art anti-C5 antibodies are disclosed in paragraphs 130, 172, 174, 178, 183, 205, and 527 of Schwaeble.

Ex parte Chamberlain, 2022-001944

Results of Initial Appeal

- New grounds of rejection under 35 U.S.C. § 112(a) and 112(b) is added.
- The obviousness-type double-patenting rejection of claims 8 and 9 based on the '818 patent is affirmed, as the PTAB holds that the '818 patent claims disclose the same mutated F c employed in the instant claims. The Examiner gave an explicit reason to use this variant in an anti-C5 antibody.
- The obviousness-type double-patenting rejection of claims 8 and 9 based on the '543 patent is reversed, as the PTAB found the Examiner did not provide a persuasive reason for conjugating a drug to soluble C5.

Ex parte Chamberlain, 2022-001944

Appellant's Request for Rehearing

- The request for rehearing is denied.
- The issue in the appeal is whether it is necessary to consider the claim preamble when determining compliance with the written description requirement of section 112(a).
- The determination that a claim preamble does not limit the scope of the claim for prior art purposes does not mean the preamble can be ignored when ascertaining whether the claim complies with the written description requirement.

Ex parte Chamberlain, 2022-001944

- Where the inventors regard their invention as "a method of treating a patient by administering an anti-C5 antibody with an Fe domain," they have the statutory burden under the written description requirement of section 112(a) to describe such a method, including the treating aspect of the claim recited in the claim preamble.

Ex parte Chamberlain, 2022-001944

- "[An intended] use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates. But as we explained in Griffin v. Bertina, 285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002), preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise." *Boehringer Ingelheim Vetmedica, Inc. v. ScheringPlough Corp*., 320 F.3d 1339, 1345 (Fed. Cir. 2003):

Ex parte Chamberlain, 2022-001944

- To determine "the essence of the invention," the PTAB turns to the specification, consistent with the need to consult the specification when determining the broadest reasonable interpretation of a claim.
- The PTAB holds that the purpose of increasing the binding and half-life of the Fc region of the antibody is to improve its efficacy when administered to a human as a therapeutic agent.
- The PTAB further holds that the specification makes it clear that the "essence of the invention" is an improved F c domain of an antibody to use the antibody therapeutically to treat a human patient.
- Consistently, the claim preamble recites "a method of treating a patient." Treatment is not merely a context in which the F c domain is useful, but instead it is "the raison d'etre (main reason) of the claimed method itself."

Ex parte Chamberlain, 2022-001944

- Therefore, claims 8 stills stand rejected under the written description requirement of section 112(a). Claim 9 still stands rejected under 35 U.S.C. § 112(a) as lacking a written description and under 35 U.S.C. § 112(b) as indefinite.
- Claims 8 and 9 still stand rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as obvious in view of claims 1-5 of the combination of the '818 patent claims and Schwaeble.
- PTAB holds that they did not overlook the asserted deficiency in the prima facie case nor the Examiner's reason to combine the '818 patent claims and Schwaeble.
- Accordingly, PTAB denies the request for rehearing.

Ex parte Chamberlain, 2022-001944

Appeal Review Panel Decision

- The ARP decision was issued by KATHERINE K. VIDAL, (ex)Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, VAISHALI UDUPA, Commissioner for Patents, and SCOTT R. BOALICK, Chief Administrative Patent Judge.
- The Director convened this Appeals Review Panel to clarify the Office's position and issue a revised decision on the proper analysis of Jepson and means-plus-function claims in this case.

Ex parte Chamberlain, 2022-001944

Recap

- Claims 8 and 9 stand rejected under 35 U.S.C. § 112, first paragraph (written description, entering new ground of rejection).
- • Claim 9 stands rejected under 35 U.S.C. § 112, second paragraph (indefiniteness, entering new ground of rejection).
- • Claims 8 and 9 stand rejected for non-statutory obviousness type double patenting over claims 1-5 of U.S. Patent 10,336,818 ("the '818 patent") and Schwaeble.
- • Claims 8 and 9 were rejected for non-statutory obviousness type double patenting over claim I of U.S. Patent 8,546,543 ("the '543 patent") and Schwaeble.

Ex parte Chamberlain, 2022-001944

- The ARP maintains the Board's new ground of rejection of claims 8 and 9 for lack of written description but does not maintain the Board's new ground of rejection of claim 9 for indefiniteness.
- The ARP further reverses the Examiner's obviousness-type double patenting rejection of claims 8 and 9 over claims 1-5 of the '818 patent and Schwaeble.
- Finally, the ARP adopts the Board's decision reversing the Examiner's obviousness-type double patenting rejection of claims 8 and 9 over claim 1 of the '543 patent and Schwaeble.

Ex parte Chamberlain, 2022-001944

Written Description of Claim 8

- The ARP determined that the preamble of claim 8 is entitled to patentable weight.
- The ARP further determined that the specification of the '690 application does not provide adequate written description support for the broad genus of any "anti-C5 antibody" and does not provide adequate written description support for "treating a patient" as broadly claimed.
- The ARP therefore maintains the Board's rejection of claim 8 for lack of adequate written description under 35 U.S.C. § 112, first paragraph.

Ex parte Chamberlain, 2022-001944

- The ARP finds the entire preamble of claim 8 to be limiting, and therefore the entire preamble requires written description support.
- As to claim construction, Appellant admits that the "administering“ portion of the claim 8 preamble is limiting.
- In doing so, Appellant acknowledges that the "administering" portion of the preamble "provides antecedent basis to the remaining claim limitations and provides the structural component ... upon which the claimed improvement in the F c region is implemented." Id.
- The Federal Circuit has "repeatedly held a preamble limiting when it serves as antecedent basis for a term appearing in the body of a claim." In re Fought, 941 F.3d 1175, 1178 (Fed. Cir. 2019).
- Claim 8 includes limitations directed to "said Fe domain" and "said anti-C5 antibody" that each find their antecedent basis in the "administering" portion of the preamble. Therefore, the preamble is limiting.

Ex parte Chamberlain, 2022-001944

- Claim 8 recites "an anti-C5 antibody," i.e., an antibody that binds C5. The only disclosure in the specification of "an anti-C5 antibody" is "anti-complement (C5) antibodies such as 5G 1.1." Spec., paragraph 133. Thus, 5G 1.1 is the only specifically disclosed example of an anti-C5 antibody.
- The ARP agrees with the Examiner that, in contrast to this limited disclosure of 5G 1.1, the genus of anti-C5 antibodies is a broad genus because it encompasses various specificities and epitopes.
- Accordingly, the ARP holds that Appellant has not shown that it was in possession of "an anti-C5 antibody" at the time of filing. Thus, the ARP concludes the term lacks adequate written description support.

Ex parte Chamberlain, 2022-001944

Written Description and Indefiniteness of Claim 9

- The ARP first determines that the limitation "treating a patient" in the preamble of the claim 9 is entitled to patentable weight, just as for claim 8.
- Because the claim phrase “treating a patient” is undefined in the specification for the same reasons as claim 8, the ARP maintains the rejection of claim 9 under 35 U.S.C. § 112, first paragraph.

Ex parte Chamberlain, 2022-001944

- Next, the ARP also determines that the phrase "means for binding human C5 protein" is a means-plus-function limitation subject to 35 U.S.C. § 112(f).
- Although the ARP also determines that the phrase "means for binding human C5 protein" is a means-plus-function limitation subject to 35 U.S.C. § 112(f), the ARP finds that a person of ordinary skill in the art would have known the structure of 5G 1.1 based on the teachings in the prior art, and thus the "means for binding human C5 protein" is adequately described in the specification.
- Specifically, the term 5G 1.1 was used to refer to eculizumab, a humanized antibody developed by Alexion, which was also known in the prior art, and the record indicates that the term 5G 1.1 was originally understood to refer to a particular mouse monoclonal antibody, which was produced from a deposited hybridoma.

Ex parte Chamberlain, 2022-001944

- Accordingly, the ARP finds the term "means for binding human C5 protein“ definite and withdraws the Board's rejection for claim 9 on indefiniteness grounds.

Ex parte Chamberlain, 2022-001944

Obvious Double-type Patenting Rejection of Claims 8 and 9

- Next, the Appellant argues that the Examiner failed to adequately provide support for the assertion that a person of skill in the art would have been motivated to make such a combination, let alone that such a combination would have had a reasonable expectation of success.
- The ARP states that the paragraphs of Schwaeble relied upon by the Examiner for considerations of half-life do not disclose Fe mutations M428L/N434S as a way to increase half-life. The cited paragraphs of Schwaeble disclose, *inter alia*, using peptide inhibitors, flanking sequences of RNA or DNA, or polymers such as polyethylene glycol, but do not disclose using the recited mutations as a way to increase half-life.
- Therefore, both double-patenting rejections are withdrawn,

Ex parte Chamberlain, 2022-001944

- Because *Ex parte* Chamberlain, 2022-001944 was not designated as either a precedential or informative designation, therefore, it is merely a routine decision.
- Stakeholders and the public may submit nominations for precedential or informative designation using the PTAB Decision Nomination web form, or by sending an email to PTAB_Decision_Nomination@uspto.gov.

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