CERTIFICATE OF FILING

The undersigned certifies that an original and three copies of the paper entitled "**NOTICE OF CROSS APPEAL**" along with copies of the documents referred therein as being submitted and the docketing fee of $450.00 were filed this 18th day of January, 2011, by Federal Express overnight delivery service, to:

Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

1-18-11
Date

Oliver R. Ashe, Jr.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the paper entitled "**NOTICE OF CROSS-APPEAL**" and a copy of the documents referred therein as being submitted were served this 18th day of January, 2011, by sending in the following manner:

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Paper 80

Filed August 30, 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261).

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY,
Administrative Patent Judges

LANE, *Administrative Patent Judge*

ORDER - DECISION ON MOTIONS

I. STATEMENT OF THE CASE

The interference is before a panel for consideration of non-priority motions filed by Carter. No oral argument was held.

The Interference

Parties

The Interference involves junior party Carter and senior party Adair.

Junior party Carter is involved on the basis of its patent 6,407,213 ("the Carter '213 patent"), which issued 18 June 2002, from application no. 08/146,206, filed 17 November 1993. (Paper 1 at 3.) Claims 30, 31, 60, 62, 63, 66, 67, 70, 73, and 77-81 were designated as corresponding to the Count, while claims 1-29, 32-59, 61, 64, 65 68, 69, 71, 72, 74-76, and 82 were not. (Paper 1 at 4.)

The real party-in-interest of Carter is Genentech, Inc. (Paper 10).

Senior party Adair is involved on the basis of its application 11/284,261 ("Adair '261 application"), filed 21 November 2005. (Paper 1 at 3.) Claim 24, Adair's only pending claim, was designated as corresponding to the Count. (Paper 1 at 4.)

Adair was accorded priority benefit as to the Count of 08/846,658, filed 01 May 1997; 08/303,569, filed 07 September 1994, issued as 5,859,205 on 12 January 1999; 07/743,329, filed on 17 September 1991 ("the Adair '329 application"); PCT/GB90/02017, filed 21 December 1990 ("the Adair PCT application"); and GB 8928874.0, filed 21 December 1989. (Paper 1 at 5.)

The real party-in-interest of Adair is UCB Pharma, S.A. (Paper 4.)

Subject Matter

The parties' claims are drawn to an antibody that has been "humanized," that is, it has a combination of human and non-human regions and specific amino acids. Humanization allows antibodies to be raised, in the laboratory, in non-human animals (for example, mice) against antigens of interest and then changed so that they appear to the patient's body as if they were human antibodies. Humanized antibodies are beneficial because they do not raise dangerous anti-immunoglobulin responses in human patients, as non-human antibodies can. (Carter patent col. 1, l. 52, through col. 3, l. 8.) The humanized antibody of the involved Carter and Adair claims and the Count are antibodies that have a non-human Complementarity Determining Region ("CDR"), that is the region that binds antigen, and specifically recited non-human substitutions in other regions, called the Framework Regions ("FR"), of the antibody.

II. MOTIONS

Carter filed two substantive motions, which assert "threshold" issues that end the interference if the relief requested is granted. Carter Substantive Motion 1 ("Carter Motion 1") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 135(b)(1). Carter Substantive Motion 2 ("Carter Motion 2") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 112, first paragraph, for a lack of written description in the specification. As the moving party, Carter has the burden to show that it is entitled to the relief requested in its motions. Bd. R. 208(b).

A. CARTER MOTION 1

Findings of Fact

1. The involved Carter '213 patent issued 18 June 2002. (Carter Ex. 2001; Carter involved '231 patent.)

2. The "critical date," under 35 U.S.C. § 135(b)(1), by which Adair must have filed claims drawn to the same or substantially the same subject matter as the claims of the Carter '213 patent is 18 June 2003.

3. Adair filed the involved Adair '261 application on 21 November 2005, after the critical date. (Ex. 2002, Utility Patent Application Transmittal for Application 11/284,261.)

4. Claim 24, the only claim pending in the Adair '261 application was filed well after the critical date.

5. Claim 24 of the involved Adair '261 application recites:

> A humanised antibody comprising a heavy chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78, and combinations thereof, as numbered according to Kabat.

(Paper 5.)

6. None of the claims of the Adair PCT application or the Adair '329 application are identical to claim 24 of the involved Adair '261 application. (Adair response to Carter MF 42; citing Exs. 2005-2010, 2012-2022, 2024-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opposition 1 at 21 ("Adair Opp. 1")), but no claims identical to claim 24 of the involved Adair '261 application identified by

Adair.)

7. In its request for interference, Bd. R. 202, Adair identified claims 8 and 16 of the Adair PCT application as a basis for compliance with 35 USC §135(b).

(Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

8. Claim 8 of the Adair PCT and '261 applications recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(Ex. 2005, p. 68 and Ex. 2006, p. 68.)

9. Claim 16 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(Ex. 2005, p. 69 and Ex. 2006, p. 69.)

10. Claim 1 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2005, p. 67 and Ex. 2006, p. 67.)

Analysis

35 U.S.C. § 135(b)(1) states that:

> [a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Claim 24 of Adair's involved application, which corresponds to the Count, was filed more than one year from the date on which Carter's involved patent was issued. Because of the date Adair claim 24 was filed (*see* FF 4), it is, on its face, barred under 35 USC §135(b).

The bar of 35 USC §135(b) might be avoided if Adair had filed a claim that does not differ materially from claim 24. Indeed, in its request for interference, Bd. R. 202, Adair pointed to claims 8 and 16 of its pre-critical date application to support its assertion that claim 24 is not barred under the statute. (FF 7; Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

"To establish entitlement to the earlier effective date of existing claims for purposes of the one-year bar of 35 U.S.C. § 135(b), a party must show that the later filed claim does not differ from an earlier claim in any 'material limitation,'" *In re Berger*, 279 F.3d 975, 981-82 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765-66 (CCPA 1977)). *See also Regents of Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371, 1375 (Fed. Cir. 2006) ("When a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for section 135(b)(1), [the Federal Circuit] applies the material differences test discussed in opinions like *Berger* to determine if

'such a claim' is barred."). The addition of a limitation for the purpose of making a claim patentable is strong evidence that the limitation is a material one. *See Corbett*, 568 F.2d at 765 (where a party's claim lacked a method step, the court noted that the party did "not seriously contend that this [was] not a material limitation, that [was] necessary to patentability . . . ."); *see also Wetmore v. Miller*, 477 F.2d 960, 964 (CCPA 1973) ("the 'fusible' limitation of appellant's claims must be regarded as not necessary to patentability and not 'material' for present purposes [of complying with 35 U.S.C. § 135(b)]").

Carter argues that the pre-critical date claims of Adair include different material limitations than those in Adair's involved claim 24. (Carter Motion 1 at 3.)

Claim 8 of the Adair PCT application, which is identical to claim 8 of the Adair '329 application, recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(FF 8; Ex. 2005, p. 68; Ex. 2006, p. 68.) Claim 16 of the Adair PCT application, which is identical to claim 16 of the Adair '329 application, recites:

> A CDR-grafted antibody heavy or light chain or molecule according to anyone of the preceding claims comprising human acceptor residues and non-human donor residues.

(FF 9; Ex. 2005, p. 69; Ex. 2006, p. 69.) Thus, the claims that Adair relied upon for avoiding the 35 U.S.C. § 135(b) bar are drawn to a CDR-grafted light chain. Adair's involved claim 24, though, is drawn to a "humanized antibody comprising a heavy chain variable domain . . . ." (FF 5, Paper 5.) Involved claim 24 differs from original claims 8

and 16, by reciting a heavy chain variable domain instead of a light chain variable domain.

Adair does not dispute that claims reciting a heavy chain and claims reciting a light chain differ materially. Instead, Adair argues that Carter applied the incorrect standard for assessing whether a post-critical date claim differs materially from an earlier claim. According to Adair, the correct inquiry is whether Adair added or removed claim limitations after the critical date that were necessary to the patentability of *Carter's* claims, not Adair's own pre-critical date claims (Adair Opp. 1 at 6).

We disagree. A party seeking support from pre-critical date claims for interfering claims filed beyond the one-year bar of 35 U.S.C. § 135(b)(1) "must demonstrate that claims in [the pre-critical date] application provide pre-critical date support for the post-critical date identity between [the involved claim] and the [patentee's patent]. That demonstration necessarily entails a comparison between pre- and post-critical date claims." *Regents of Univ. of Cal.*, 455 F.3d at 1375.

Adair also argues, in response to Carter's assertion of the material differences between claims to heavy and light chains, that in addition to its claims drawn to light chains, Adair filed claims drawn to heavy chains before the critical date. Specifically, Adair cites claim 1 of its PCT application as claiming a CDR-grafted antibody heavy chain, and argues that it, together with claim 16, effectively contain all of the limitations of involved claim 66 of the Carter '213 patent. (Adair Opp. 1 at 5; *see* FF 10; Ex. 2005, p. 67; Ex. 2006, p. 67.).[1]

---

1 Similarly in its showing under Bd. R. 202, Adair compared its pre-critical date claims to a Carter claim but not the current Adair claim. (Ex. 2003, Adair's Preliminary Amendment and Request for

Adair has not made the correct comparison. Under the guidance provided in *Regents of University of California*, Adair's pre-critical date claims must be compared with its own current claims, not Carter's. Thus we are not persuaded by Adair's argument that it is sufficient that it had on file a claim or claims that effectively contain the limitations of an involved Carter claim.

Even when we consider claims 1 and 16 of the PCT application as they compare to Adair's current claim (and not Carter claim 66 as Adair argues), we are not convinced that Adair had a pre-critical date claim that does not differ materially from its current claim. As Carter notes, (1) claims 1 and 16 of Adair's PCT application were rejected under several statutory grounds in the Adair '329 application, including 35 U.S.C. §§ 101, 112, first and second paragraphs, 102(b), and 103(a), (*see* Ex. 2038, Office Action mailed 18 November 1992), and (2) Adair then cancelled the claims and added new ones that were eventually allowed (Ex. 2007, Amendment of 19 January 1993, p. 2). (*See* Carter Motion 1 at 5-6.)

One example of a material limitation is one that is "necessary to patentability." *See Corbett*, 568 F.2d at 765. When an applicant adds a limitation to a claim in response to a rejection and the added limitation results in allowance of the claim, the limitation is presumed to be necessary to patentability. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 734 (2002) (in the context of applying the doctrine of equivalents, "[a] rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession

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Interference under 37 C.F.R. § 42.202, p. 5.)

that the invention as patented does not reach as far as the original claim."); *see Berger*, 279 F.3d at 982 ("Inclusion of a limitation in a claim to avoid the prior art provides strong evidence of the materiality of the included limitation."). Adair does not provide any reason why the limitations that differ between involved claim 24 and original claims 1 and 16 were not necessary to the patentability of claim 24. Nor does Adair point to any other pre-critical date claim that is identical to or includes the same material limitations as its involved claim 24. (FF 6; *see* Carter MF 42, citing Exs. 2005-2010, 2013-2022, 2025-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opp. 1 at 21), but no claims identical to claim 24 of the involved Adair '261 application identified by Adair). We also note that as an applicant Adair could have, but did not, seek authorization to file a motion to add to its application a pre-critical date claim that interferes with the Carter claims (See Papers 23 and 73 (Orders setting times)).

Adair questions how one can provoke an interference if any claim amendments were made during prosecution under the standard stated in *Regents of University of California.* (Adair Opp. 1 at 7.) As explained in that case, "section 135(b)(1) [is] a statute of repose, placing a time limit on a patentee's exposure to an interference proceeding. *Regents Univ. of Cal.*, 455 F.3d at 1376. Despite this statute of repose, a "belated interference", i.e., based on a post-critical date claim, is appropriate in certain instances since "[t]he PTO should declare a valid interference upon receipt of a claim that satisfies section 135(b)(1), and which is otherwise patentable." (*Id.* at 1376). To insure that applicant did indeed timely present a patentable interfering claim, the post-critical date claim in interference must be materially the same as the claim that was timely presented. An applicant cannot expect to avoid the bar of §135(b) by timely

copying a claim from an issued patent when that claim is not patentable to that applicant. As the court noted, it "perceives no inequity in a construction of section 135(b)(1) that might, in some circumstances, prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled." (*Id.* at 1377).

We grant Carter Motion 1 and conclude that Adair involved claim 24 is barred under 35 U.S.C. § 135(b)(1).

B. CARTER MOTION 2

Carter asserts that claim 24 of Adair's involved application is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description support.

Findings of Fact

11. Adair's specification provides a "preferred protocol" to determine which residues of a human heavy chain should be substituted for donor residues, as follows

> 2. Heavy Chain
>
> 2.1 Choose donor residues at all of positions 23, 24, 49, 71, 73 and 78 of the heavy chain or all of positions 23, 24 and 49 (71, 73 and 78 are always either all donor or all acceptor).
>
> 2.2 Check that the following have the same amino acid in donor and acceptor sequences, and if not preferably choose the donor: 2, 4, 6, 25, 36, 37, 39, 47, 48, 93, 94, 103, 104, 106 and 107.

(Ex. 2002, pp. 17-18; MF 13.)

12. Adair's specification includes the following directions regarding substituting residues of a human heavy chain for donor residues:

> "Key residues" near the surface of the heavy chain, are residues 23, 71 and 73, with residues 1, 3, and 76 reported to contribute to a lesser extent. (Ex. 2002, p. 20; MF 16.)

"Key residues" among the "[p]acking residues" near the CDRs as 24, 49, and 78. (Ex. 2002, p. 21; MF 17.)

Example 1 reports that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78." (Ex. 2002, p. 52; MF 19.)

Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 only was found to be important for antigen binding. (Ex. 2002, pp. 57-58; MF 56.)

13. Adair's specification provides the following written description of a CDR-grafted antibody heavy chain with specified donor residues:

> Accordingly, in a first aspect the invention provides a CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2002 at p. 6.)

14. Adair's specification also provides the following written description of a CDR- grafted antibody heavy chain with specified donor residues:

> In preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues.

(Ex. 2002 at p. 7.)

15. Adair's specification states:

> A preferred protocol for obtaining CDR-grafted antibody heavy and light chains in accordance with the present invention is set out below together with the rationale by which we have derived this protocol. This protocol. and rationale are given without prejudice to the generality of the invention as hereinbefore described and defined.

(Ex. 2002, p. 16; MF 53.)

Analysis

The test for written description under 35 U.S.C. § 112, first paragraph, "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc., v. Eli Lilly & Co.*, 598 F3d 1336, 1351 (Fed. Cir. 2010). This analysis must consider the understandings of those in the art at the time of filing, *see Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125-26 (Fed. Cir. 2004), and must consider the specification as a whole, *see In re Wright*, 866 F.2d 422, 424-25 (Fed. Cir. 1989).

Claim 24 recites a humanized antibody with a heavy chain "compris[ing] a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78 and combinations thereof . . . ." (FF 5; Paper 5). As Carter asserts, the broadest reasonable interpretation of this language in claim 24 encompasses a human heavy chain with residue substitutions at any number of the six residues recited, for example at only one residue, at all six residues, or at any combination in between. (*See* Carter Motion 2 at 1 and 5-6.)

Specification

In support of its argument that Adair's specification does not provide written description support of *any* of the six residues in claim 24, Carter cites to a "preferred protocol" provided in Adair's specification. Carter asserts that this protocol limits the invention to a human heavy chain framework region with either all of residues 23, 24, and 49, or all of residues 23, 24, 29, 71, 73, and 78, but not any of the residues individually. (Carter Motion 2 at 2 and 8; FF 11; Ex. 2002, Adair Specification, pp. 17-

18.) While this portion of the Adair specification appears to exclude many of combinations of substitutions encompassed by claim 24, other portions of Adair's specification are not so limiting.

For example, elsewhere Adair's specification provides that some "key residues" for making humanized antibodies are 23, 71 and 73, while other "key residues" are 24, 49, and 78. (FF 12; Ex. 2002, pp. 20 and 21; *see* Carter Motion 2 at 3.) Carter does not point to language in this part of the specification that indicates residues 23, 24, and 49 must *all* be substituted together or that 23, 24, 49, 71, 73, and 78 must *all* be substituted together.

In addition, while Carter cites Example 1 as reporting that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78" (FF 12: Ex. 2002, p. 52; *see* Carter Motion 2 at 3), Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 *only* was important for antigen binding. (FF 12; Ex. 2002, pp. 57-58; *see* Adair Opposition 2 at 3-4 ("Adair Opp. 2").) Thus, not all of the examples in Adair's specification support Carter's argument of a requirement for substation of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78.

Carter points to the Summary of the Invention section of Adair's application, which provides that human residues of the heavy chain can be substituted for donor residues at "at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91." (Carter Motion 2 at 6; FF 13; Ex. 2002, p. 6.) According to Carter, this language does not provide written description because it is "ambiguous." (Carter Motion 2 at 6-8.) As evidence, Carter points to the rejection

under 35 U.S.C. § 112, second paragraph, of original claim 1 in the Adair '329 application, which contained this language from the Adair specification, and Adair's response canceling claim 1. (Carter Motion 2, MFs 22 and 25; Ex. 2007, p. 29-32; Ex. 2038, p. 6.)

We do not agree that the rejection under the second paragraph of § 112 necessarily shows a lack of written description support under the first paragraph of § 112. Carter's analysis lacks a consideration of the entire Adair specification and instead focuses only upon an isolated portion.

Carter points to another part of the Summary of the Invention, wherein "[i]n preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues." (FF 14; Ex. 2002 at p. 7; *see* Carter Motion 2 at 8.) Carter characterizes this portion as providing that 71, 73, and 78 "must" be either all acceptor or all donor residues (Carter Motion 2 at 8), but the passage expressly states that positions 71, 73, and 78 are "preferably" all donor or all acceptor. Thus, this portion of Adair's specification is not as limited as Carter asserts.

It does not appear to us that, on its face, the Adair specification contains a requirement for substitution of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78. Carter does not direct us to the testimony or other evidence showing what the Adair specification would have conveyed to those skilled in the art at the time of filing such that we might find otherwise. "Argument of counsel cannot take the place of evidence lacking in the record." *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA

1977).

Prosecution History

Carter also points to the prosecution of Adair's applications as evidence that claim 24 is not supported by the Adair specification. According to Carter, Adair relied on the "preferred protocol" to distinguish claims of the Adair '329 application over the prior art and to overcome rejections for lack of enablement. (Carter Motion 2 at 9-13). The rejections, amendments, and arguments relied upon by Carter were not directed to involved claim 24 and Carter does not provide a detailed analysis of the claims that were being prosecuted and their relationship to Adair's current claim 24. Thus it is difficult to understand the relevance of the rejection of these claims to involved claim 24. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250, n.2 (Fed. Cir. 2008) ("Judges are not like pigs, hunting for truffles buried in briefs." (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991)).

In addition, though Carter notes instances when Adair discussed the "preferred protocol" and other rules for determining which residues to substitute, Carter does not point to instances where Adair argues that these are the *only* disclosures in their specification. In fact, other portions of the specification indicate that this "preferred protocol" is not limiting on the invention. (*See* Adair Opp. 2 at 3-4; FFs 15 and 16; Ex. 2002, Adair Specification, pp. 16 and 64.)

Carter has not shown that Adair claim 24 lacks sufficient written description support.

III. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Carter Motion 1 for judgment that Adair claim 24 is barred under 35 U.S.C. § 135(b) is GRANTED; and

FURTHER ORDERED that Carter Motion 2 for judgment that Adair claim 24 lacks written description support is DENIED; and

FURTHER ORDERED that judgment will be entered against Adair in a separate paper.

/ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
Administrative Patent Judge

/ss/ Sally C. Medley
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Paper 81

Filed 2 September 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTIA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILGEET SINGH ATHWAL,
and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

Judgment– Merits – Bd. R. 127

The Carter motion for judgment on the basis that the single involved Adair claim is barred under 35 U.S.C. § 135(b) was granted. (Paper 80). Because Adair no longer has an interfering claim that is not barred under 35 U.S.C. §135(b) it is appropriate to

enter judgment against Adair. *Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002).

It is

ORDERED that judgment on priority as to Count 1 (Paper 1 at 4), the sole count of the interference, is entered against senior party Adair;

FURTHER ORDERED that claim 24 of Adair application 11/284,261, which claim corresponds to Count 1 (Paper 1 at 4), is FINALLY REFUSED, 35 U.S.C. §135(a):

FURTHER ORDERED that if there is a settlement agreement, the parties are directed to 35 U.S.C. 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of the Carter involved patent and application and the Adair involved application.

cc (via electronic filing):

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(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILJEET SINGH ATHWAL,
AND JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

ADAIR NOTIFICATION OF NOTICE OF APPEAL

In accordance with Bd. R. 8(b) and SO ¶ 8.3, please find enclosed a copy of the Notice of Appeal to the Court of Appeals for the Federal Circuit, and accompanying papers, filed by Adair on January 4, 2011.

Respectfully submitted,

/Doreen Yatko Trujillo/
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Certificate of Service

This will certify that true copies of this paper and accompanying documents were served this date, January 19, 2011, via electronic mail, on the Lead Counsel for Cabilly:

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, AND JOHN SPENCER EMTAGE Appellants vs. PAUL J. CARTER AND LEONARD G. PRESTA Appellees	**NOTICE OF APPEAL**

Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage hereby appeal to the United States Court of Appeals for the Federal Circuit from the following orders, decisions, and/or judgments rendered by the Board of Patent Appeals and Interferences in Interference No. 105,744: (i) Order -- Decision on Motions, entered August 30, 2010 (Paper No. 80); (ii) Judgment – Merits – Bd. R. 127, entered September 2, 2010 (Paper No. 81); and (iii) Order -- Decision on Adiar [sic] Request for Rehearing, entered November 5, 2010 (Paper No. 84). Copies of each are enclosed.

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CERTIFICATE OF SERVICE

Doreen Yatko Trujillo, attorney for appellants, hereby certifies that a true and correct copy of the foregoing **Notice of Appeal, and accompanying papers,** was served this day, January 4, 2011, via Federal Express on the following:

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Paper 80

Filed August 30, 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261).

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY,
Administrative Patent Judges

LANE, *Administrative Patent Judge*

ORDER - DECISION ON MOTIONS

I. STATEMENT OF THE CASE

The interference is before a panel for consideration of non-priority motions filed by Carter. No oral argument was held.

The Interference

Parties

The Interference involves junior party Carter and senior party Adair.

Junior party Carter is involved on the basis of its patent 6,407,213 ("the Carter '213 patent"), which issued 18 June 2002, from application no. 08/146,206, filed 17 November 1993. (Paper 1 at 3.) Claims 30, 31, 60, 62, 63, 66, 67, 70, 73, and 77-81 were designated as corresponding to the Count, while claims 1-29, 32-59, 61, 64, 65 68, 69, 71, 72, 74-76, and 82 were not. (Paper 1 at 4.)

The real party-in-interest of Carter is Genentech, Inc. (Paper 10).

Senior party Adair is involved on the basis of its application 11/284,261 ("Adair '261 application"), filed 21 November 2005. (Paper 1 at 3.) Claim 24, Adair's only pending claim, was designated as corresponding to the Count. (Paper 1 at 4.)

Adair was accorded priority benefit as to the Count of 08/846,658, filed 01 May 1997; 08/303,569, filed 07 September 1994, issued as 5,859,205 on 12 January 1999; 07/743,329, filed on 17 September 1991 ("the Adair '329 application"); PCT/GB90/02017, filed 21 December 1990 ("the Adair PCT application"); and GB 8928874.0, filed 21 December 1989. (Paper 1 at 5.)

The real party-in-interest of Adair is UCB Pharma, S.A. (Paper 4.)

Subject Matter

The parties' claims are drawn to an antibody that has been "humanized," that is, it has a combination of human and non-human regions and specific amino acids. Humanization allows antibodies to be raised, in the laboratory, in non-human animals (for example, mice) against antigens of interest and then changed so that they appear to the patient's body as if they were human antibodies. Humanized antibodies are beneficial because they do not raise dangerous anti-immunoglobulin responses in human patients, as non-human antibodies can. (Carter patent col. 1, l. 52, through col. 3, l. 8.) The humanized antibody of the involved Carter and Adair claims and the Count are antibodies that have a non-human Complementarity Determining Region ("CDR"), that is the region that binds antigen, and specifically recited non-human substitutions in other regions, called the Framework Regions ("FR"), of the antibody.

II. MOTIONS

Carter filed two substantive motions, which assert "threshold" issues that end the interference if the relief requested is granted. Carter Substantive Motion 1 ("Carter Motion 1") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 135(b)(1). Carter Substantive Motion 2 ("Carter Motion 2") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 112, first paragraph, for a lack of written description in the specification. As the moving party, Carter has the burden to show that it is entitled to the relief requested in its motions. Bd. R. 208(b).

A. CARTER MOTION 1

Findings of Fact

1. The involved Carter '213 patent issued 18 June 2002. (Carter Ex. 2001; Carter involved '231 patent.)

2. The "critical date," under 35 U.S.C. § 135(b)(1), by which Adair must have filed claims drawn to the same or substantially the same subject matter as the claims of the Carter '213 patent is 18 June 2003.

3. Adair filed the involved Adair '261 application on 21 November 2005, after the critical date. (Ex. 2002, Utility Patent Application Transmittal for Application 11/284,261.)

4. Claim 24, the only claim pending in the Adair '261 application was filed well after the critical date.

5. Claim 24 of the involved Adair '261 application recites:

> A humanised antibody comprising a heavy chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78, and combinations thereof, as numbered according to Kabat.

(Paper 5.)

6. None of the claims of the Adair PCT application or the Adair '329 application are identical to claim 24 of the involved Adair '261 application. (Adair response to Carter MF 42; citing Exs. 2005-2010, 2012-2022, 2024-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opposition 1 at 21 ("Adair Opp. 1")), but no claims identical to claim 24 of the involved Adair '261 application identified by

Adair.)

7. In its request for interference, Bd. R. 202, Adair identified claims 8 and 16 of the Adair PCT application as a basis for compliance with 35 USC §135(b).

(Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

8. Claim 8 of the Adair PCT and '261 applications recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(Ex. 2005, p. 68 and Ex. 2006, p. 68.)

9. Claim 16 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(Ex. 2005, p. 69 and Ex. 2006, p. 69.)

10. Claim 1 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2005, p. 67 and Ex. 2006, p. 67.)

Analysis

35 U.S.C. § 135(b)(1) states that:

> [a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Claim 24 of Adair's involved application, which corresponds to the Count, was filed more than one year from the date on which Carter's involved patent was issued. Because of the date Adair claim 24 was filed (*see* FF 4), it is, on its face, barred under 35 USC §135(b).

The bar of 35 USC §135(b) might be avoided if Adair had filed a claim that does not differ materially from claim 24. Indeed, in its request for interference, Bd. R. 202, Adair pointed to claims 8 and 16 of its pre-critical date application to support its assertion that claim 24 is not barred under the statute. (FF 7; Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

"To establish entitlement to the earlier effective date of existing claims for purposes of the one-year bar of 35 U.S.C. § 135(b), a party must show that the later filed claim does not differ from an earlier claim in any 'material limitation,'" *In re Berger*, 279 F.3d 975, 981-82 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765-66 (CCPA 1977)). *See also Regents of Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371, 1375 (Fed. Cir. 2006) ("When a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for section 135(b)(1), [the Federal Circuit] applies the material differences test discussed in opinions like *Berger* to determine if

'such a claim' is barred."). The addition of a limitation for the purpose of making a claim patentable is strong evidence that the limitation is a material one. *See Corbett*, 568 F.2d at 765 (where a party's claim lacked a method step, the court noted that the party did "not seriously contend that this [was] not a material limitation, that [was] necessary to patentability . . . ."); *see also Wetmore v. Miller*, 477 F.2d 960, 964 (CCPA 1973) ("the 'fusible' limitation of appellant's claims must be regarded as not necessary to patentability and not 'material' for present purposes [of complying with 35 U.S.C. § 135(b)]").

Carter argues that the pre-critical date claims of Adair include different material limitations than those in Adair's involved claim 24. (Carter Motion 1 at 3.)

Claim 8 of the Adair PCT application, which is identical to claim 8 of the Adair '329 application, recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(FF 8; Ex. 2005, p. 68; Ex. 2006, p. 68.) Claim 16 of the Adair PCT application, which is identical to claim 16 of the Adair '329 application, recites:

> A CDR-grafted antibody heavy or light chain or molecule according to anyone of the preceding claims comprising human acceptor residues and non-human donor residues.

(FF 9; Ex. 2005, p. 69; Ex. 2006, p. 69.) Thus, the claims that Adair relied upon for avoiding the 35 U.S.C. § 135(b) bar are drawn to a CDR-grafted light chain. Adair's involved claim 24, though, is drawn to a "humanized antibody comprising a heavy chain variable domain . . . ." (FF 5, Paper 5.) Involved claim 24 differs from original claims 8

and 16, by reciting a heavy chain variable domain instead of a light chain variable domain.

Adair does not dispute that claims reciting a heavy chain and claims reciting a light chain differ materially. Instead, Adair argues that Carter applied the incorrect standard for assessing whether a post-critical date claim differs materially from an earlier claim. According to Adair, the correct inquiry is whether Adair added or removed claim limitations after the critical date that were necessary to the patentability of *Carter's* claims, not Adair's own pre-critical date claims (Adair Opp. 1 at 6).

We disagree. A party seeking support from pre-critical date claims for interfering claims filed beyond the one-year bar of 35 U.S.C. § 135(b)(1) "must demonstrate that claims in [the pre-critical date] application provide pre-critical date support for the post-critical date identity between [the involved claim] and the [patentee's patent]. That demonstration necessarily entails a comparison between pre- and post-critical date claims." *Regents of Univ. of Cal.*, 455 F.3d at 1375.

Adair also argues, in response to Carter's assertion of the material differences between claims to heavy and light chains, that in addition to its claims drawn to light chains, Adair filed claims drawn to heavy chains before the critical date. Specifically, Adair cites claim 1 of its PCT application as claiming a CDR-grafted antibody heavy chain, and argues that it, together with claim 16, effectively contain all of the limitations of involved claim 66 of the Carter '213 patent. (Adair Opp. 1 at 5; *see* FF 10; Ex. 2005, p. 67; Ex. 2006, p. 67.).[1]

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1 Similarly in its showing under Bd. R. 202, Adair compared its pre-critical date claims to a Carter claim but not the current Adair claim. (Ex. 2003, Adair's Preliminary Amendment and Request for

Adair has not made the correct comparison. Under the guidance provided in *Regents of University of California,* Adair's pre-critical date claims must be compared with its own current claims, not Carter's. Thus we are not persuaded by Adair's argument that it is sufficient that it had on file a claim or claims that effectively contain the limitations of an involved Carter claim.

Even when we consider claims 1 and 16 of the PCT application as they compare to Adair's current claim (and not Carter claim 66 as Adair argues), we are not convinced that Adair had a pre-critical date claim that does not differ materially from its current claim. As Carter notes, (1) claims 1 and 16 of Adair's PCT application were rejected under several statutory grounds in the Adair '329 application, including 35 U.S.C. §§ 101, 112, first and second paragraphs, 102(b), and 103(a), (*see* Ex. 2038, Office Action mailed 18 November 1992), and (2) Adair then cancelled the claims and added new ones that were eventually allowed (Ex. 2007, Amendment of 19 January 1993, p. 2). (*See* Carter Motion 1 at 5-6.)

One example of a material limitation is one that is "necessary to patentability." *See Corbett*, 568 F.2d at 765. When an applicant adds a limitation to a claim in response to a rejection and the added limitation results in allowance of the claim, the limitation is presumed to be necessary to patentability. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,* 535 U.S. 722, 734 (2002) (in the context of applying the doctrine of equivalents, "[a] rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession

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Interference under 37 C.F.R. § 42.202, p. 5.)

that the invention as patented does not reach as far as the original claim."); *see Berger*, 279 F.3d at 982 ("Inclusion of a limitation in a claim to avoid the prior art provides strong evidence of the materiality of the included limitation."). Adair does not provide any reason why the limitations that differ between involved claim 24 and original claims 1 and 16 were not necessary to the patentability of claim 24. Nor does Adair point to any other pre-critical date claim that is identical to or includes the same material limitations as its involved claim 24. (FF 6; *see* Carter MF 42, citing Exs. 2005-2010, 2013-2022, 2025-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opp. 1 at 21), but no claims identical to claim 24 of the involved Adair '261 application identified by Adair). We also note that as an applicant Adair could have, but did not, seek authorization to file a motion to add to its application a pre-critical date claim that interferes with the Carter claims (See Papers 23 and 73 (Orders setting times)).

Adair questions how one can provoke an interference if any claim amendments were made during prosecution under the standard stated in *Regents of University of California*. (Adair Opp. 1 at 7.) As explained in that case, "section 135(b)(1) [is] a statute of repose, placing a time limit on a patentee's exposure to an interference proceeding. *Regents Univ. of Cal.*, 455 F.3d at 1376. Despite this statute of repose, a "belated interference", i.e., based on a post-critical date claim, is appropriate in certain instances since "[t]he PTO should declare a valid interference upon receipt of a claim that satisfies section 135(b)(1), and which is otherwise patentable." (*Id.* at 1376). To insure that applicant did indeed timely present a patentable interfering claim, the post-critical date claim in interference must be materially the same as the claim that was timely presented. An applicant cannot expect to avoid the bar of §135(b) by timely

copying a claim from an issued patent when that claim is not patentable to that applicant. As the court noted, it "perceives no inequity in a construction of section 135(b)(1) that might, in some circumstances, prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled." (*Id.* at 1377).

We grant Carter Motion 1 and conclude that Adair involved claim 24 is barred under 35 U.S.C. § 135(b)(1).

B. CARTER MOTION 2

Carter asserts that claim 24 of Adair's involved application is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description support.

Findings of Fact

11. Adair's specification provides a "preferred protocol" to determine which residues of a human heavy chain should be substituted for donor residues, as follows

> 2. Heavy Chain
>
> 2.1 Choose donor residues at all of positions 23, 24, 49, 71, 73 and 78 of the heavy chain or all of positions 23, 24 and 49 (71, 73 and 78 are always either all donor or all acceptor).
>
> 2.2 Check that the following have the same amino acid in donor and acceptor sequences, and if not preferably choose the donor: 2, 4, 6, 25, 36, 37, 39, 47, 48, 93, 94, 103, 104, 106 and 107.

(Ex. 2002, pp. 17-18; MF 13.)

12. Adair's specification includes the following directions regarding substituting residues of a human heavy chain for donor residues:

> "Key residues" near the surface of the heavy chain, are residues 23, 71 and 73, with residues 1, 3, and 76 reported to contribute to a lesser extent. (Ex. 2002, p. 20; MF 16.)

"Key residues" among the "[p]acking residues" near the CDRs as 24, 49, and 78. (Ex. 2002, p. 21; MF 17.)

Example 1 reports that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78." (Ex. 2002, p. 52; MF 19.)

Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 only was found to be important for antigen binding. (Ex. 2002, pp. 57-58; MF 56.)

13. Adair's specification provides the following written description of a CDR-grafted antibody heavy chain with specified donor residues:

> Accordingly, in a first aspect the invention provides a CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2002 at p. 6.)

14. Adair's specification also provides the following written description of a CDR- grafted antibody heavy chain with specified donor residues:

> In preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues.

(Ex. 2002 at p. 7.)

15. Adair's specification states:

> A preferred protocol for obtaining CDR-grafted antibody heavy and light chains in accordance with the present invention is set out below together with the rationale by which we have derived this protocol. This protocol. and rationale are given without prejudice to the generality of the invention as hereinbefore described and defined.

(Ex. 2002, p. 16; MF 53.)

Analysis

The test for written description under 35 U.S.C. § 112, first paragraph, "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc., v. Eli Lilly & Co.*, 598 F3d 1336, 1351 (Fed. Cir. 2010). This analysis must consider the understandings of those in the art at the time of filing, *see Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125-26 (Fed. Cir. 2004), and must consider the specification as a whole, *see In re Wright,* 866 F.2d 422, 424-25 (Fed. Cir. 1989).

Claim 24 recites a humanized antibody with a heavy chain "compris[ing] a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78 and combinations thereof . . . ." (FF 5; Paper 5). As Carter asserts, the broadest reasonable interpretation of this language in claim 24 encompasses a human heavy chain with residue substitutions at any number of the six residues recited, for example at only one residue, at all six residues, or at any combination in between. (*See* Carter Motion 2 at 1 and 5-6.)

Specification

In support of its argument that Adair's specification does not provide written description support of *any* of the six residues in claim 24, Carter cites to a "preferred protocol" provided in Adair's specification. Carter asserts that this protocol limits the invention to a human heavy chain framework region with either all of residues 23, 24, and 49, or all of residues 23, 24, 29, 71, 73, and 78, but not any of the residues individually. (Carter Motion 2 at 2 and 8; FF 11; Ex. 2002, Adair Specification, pp. 17-

18.) While this portion of the Adair specification appears to exclude many of combinations of substitutions encompassed by claim 24, other portions of Adair's specification are not so limiting.

For example, elsewhere Adair's specification provides that some "key residues" for making humanized antibodies are 23, 71 and 73, while other "key residues" are 24, 49, and 78. (FF 12; Ex. 2002, pp. 20 and 21; *see* Carter Motion 2 at 3.) Carter does not point to language in this part of the specification that indicates residues 23, 24, and 49 must *all* be substituted together or that 23, 24, 49, 71, 73, and 78 must *all* be substituted together.

In addition, while Carter cites Example 1 as reporting that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78" (FF 12: Ex. 2002, p. 52; *see* Carter Motion 2 at 3), Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 *only* was important for antigen binding. (FF 12; Ex. 2002, pp. 57-58; *see* Adair Opposition 2 at 3-4 ("Adair Opp. 2").) Thus, not all of the examples in Adair's specification support Carter's argument of a requirement for substation of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78.

Carter points to the Summary of the Invention section of Adair's application, which provides that human residues of the heavy chain can be substituted for donor residues at "at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91." (Carter Motion 2 at 6; FF 13; Ex. 2002, p. 6.) According to Carter, this language does not provide written description because it is "ambiguous." (Carter Motion 2 at 6-8.) As evidence, Carter points to the rejection

under 35 U.S.C. § 112, second paragraph, of original claim 1 in the Adair '329 application, which contained this language from the Adair specification, and Adair's response canceling claim 1. (Carter Motion 2, MFs 22 and 25; Ex. 2007, p. 29-32; Ex. 2038, p. 6.)

We do not agree that the rejection under the second paragraph of § 112 necessarily shows a lack of written description support under the first paragraph of § 112. Carter's analysis lacks a consideration of the entire Adair specification and instead focuses only upon an isolated portion.

Carter points to another part of the Summary of the Invention, wherein "[i]n preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues." (FF 14; Ex. 2002 at p. 7; *see* Carter Motion 2 at 8.) Carter characterizes this portion as providing that 71, 73, and 78 "must" be either all acceptor or all donor residues (Carter Motion 2 at 8), but the passage expressly states that positions 71, 73, and 78 are "preferably" all donor or all acceptor. Thus, this portion of Adair's specification is not as limited as Carter asserts.

It does not appear to us that, on its face, the Adair specification contains a requirement for substitution of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78. Carter does not direct us to the testimony or other evidence showing what the Adair specification would have conveyed to those skilled in the art at the time of filing such that we might find otherwise. "Argument of counsel cannot take the place of evidence lacking in the record." *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA

1977).

Prosecution History

Carter also points to the prosecution of Adair's applications as evidence that claim 24 is not supported by the Adair specification. According to Carter, Adair relied on the "preferred protocol" to distinguish claims of the Adair '329 application over the prior art and to overcome rejections for lack of enablement. (Carter Motion 2 at 9-13). The rejections, amendments, and arguments relied upon by Carter were not directed to involved claim 24 and Carter does not provide a detailed analysis of the claims that were being prosecuted and their relationship to Adair's current claim 24. Thus it is difficult to understand the relevance of the rejection of these claims to involved claim 24. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250, n.2 (Fed. Cir. 2008) ("Judges are not like pigs, hunting for truffles buried in briefs." (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991)).

In addition, though Carter notes instances when Adair discussed the "preferred protocol" and other rules for determining which residues to substitute, Carter does not point to instances where Adair argues that these are the *only* disclosures in their specification. In fact, other portions of the specification indicate that this "preferred protocol" is not limiting on the invention. (*See* Adair Opp. 2 at 3-4; FFs 15 and 16; Ex. 2002, Adair Specification, pp. 16 and 64.)

Carter has not shown that Adair claim 24 lacks sufficient written description support.

III. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Carter Motion 1 for judgment that Adair claim 24 is barred under 35 U.S.C. § 135(b) is GRANTED; and

FURTHER ORDERED that Carter Motion 2 for judgment that Adair claim 24 lacks written description support is DENIED; and

FURTHER ORDERED that judgment will be entered against Adair in a separate paper.

/ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
Administrative Patent Judge

/ss/ Sally C. Medley
SALLY C. MEDLEY
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Paper 81

Filed 2 September 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTIA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILGEET SINGH ATHWAL,
and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

Judgment– Merits – Bd. R. 127

The Carter motion for judgment on the basis that the single involved Adair claim is barred under 35 U.S.C. § 135(b) was granted. (Paper 80). Because Adair no longer has an interfering claim that is not barred under 35 U.S.C. §135(b) it is appropriate to

enter judgment against Adair. *Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002).

It is

ORDERED that judgment on priority as to Count 1 (Paper 1 at 4), the sole count of the interference, is entered against senior party Adair;

FURTHER ORDERED that claim 24 of Adair application 11/284,261, which claim corresponds to Count 1 (Paper 1 at 4), is FINALLY REFUSED, 35 U.S.C. §135(a):

FURTHER ORDERED that if there is a settlement agreement, the parties are directed to 35 U.S.C. 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of the Carter involved patent and application and the Adair involved application.

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Paper 84
Filed: 5 November 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTIA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILGEET SINGH ATHWAL, and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY MEDLEY,
Administrative Patent Judges

LANE, *Administrative Patent Judge*

ORDER - DECISION ON ADIAR REQUEST FOR REHEARING

I. STATEMENT OF THE CASE

Adair filed a Request for Rehearing (Paper 83) ("Request") of our Order – Decision on Motions (Paper 80) ("Decision") granting Carter Substantive Motion 1. We considered the Request but do not modify our Decision.

II. ANALYSIS

Adair argues that we inappropriately relied on *Regents of Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371 (Fed. Cir. 2006), as the standard for determining whether Adair's involved claim 24 is barred under 35 U.S.C. § 135(b)(1). (Request 2). Adair attempts to distinguish the facts of *Univ. of Cal.* from the facts of the current interference, by noting that in *Univ. of Cal.* the claim in question was copied prior to the *pre*-critical date (and then later amended), while in the current interference the claim was copied only *after* the critical date. (Request 3). According to Adair, *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002), and *Corbett v. Chisholm*, 568 F.2d759 (CCPA 1977) are instructive under the current facts, instead of *Univ. of Cal.*

We disagree. *Univ. of Cal.* expressly denies that there is any difference under 35 U.S.C. § 135(b)(1) between a pre-critical date request for interference (where the copied claim would have been filed before the critical date) and a post-critical date request for interference (where the copied claim would have been filed after the critical date). *See Univ. of Cal.*, 455 F.3d at 1375 ("Section 135(b)(1) does not include any language suggesting that a pre-critical date request for interference makes any difference. Section 135(b)(1) bars any claim having a degree of identity with a claim in an issued patent unless such a claim is filed before the critical date. Thus, title 35 in this section does not demand notice of an impending interference, but instead prohibits

unsupported, post-critical date identity."); *see also id.* at 1374 ("this court does not perceive any legally significant distinctions between this case and [*Berger*]."). Thus, we did not err by relying on *Univ. of Cal.*

According to Adair, the only requirement under § 135(b)(1) is that the limitations of the copied patent claim are present in a pre-critical date claim. (Request 3-4). Both *Univ. of Cal.* and *Berger* explain that

> a copied claim may be entitled to the earlier effective date of prior claims in an application only if the copied claim does not differ from the prior claims in any material limitation. . . . The analysis focuses on the copied claim to determine whether all material limitations of the copied claim necessarily occur in the prior claims.

Berger, 279 F.3d at 982; *see also Univ. of Cal.*, 455 F.3d at 1375 (an applicant "must demonstrate that claims in [the pre-critical date] application provide pre-critical date support for the post-critical date identity between [the involved claim] and the [patentee's patent]. That demonstration necessarily entails a comparison between pre- and post-critical date claims."). We agree with Adair's statement that "the *Berger* test compares the pre-critical date claims and the post-critical date claims, which were copied from the patent, to ensure that all material limitations of the post-critical date claims are present in the pre-critical date claims" (Request 4). However, Adair has not pointed to support in *Berger* for its argument that "[m]ateriality is determined in view of the patent claims being copied" (*id.*). Even if Adair's claims do satisfy such a test for materiality, these claims must also satisfy the separate *Berger* and *University of California* requirements. *Berger* and *Univ. of Cal.* require that Adair's pre-critical date claims include all of the material limitations of its post-critical date claims to fulfill the requirement of 35 U.S.C. § 135(b)(1).

Adair also argues that we erred by not putting the burden on Carter to show that Adair's pre-critical date claims differ materially from its post-critical date claims. (Request 5-6). However, in its Motion (Paper 71), Carter showed that claim 24 (the copied claim) differs materially from those claims relied upon by Adair to meet the requirements of 35 U.S.C. § 135(b)(1), PCT claims 8 and 16 (*see* FF[1] 7, Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5). PCT claims 8 and 16 were directed to a CDR-grafted antibody light chain, while Adair's involved claim 24 is directed to an antibody heavy chain variable domain. (*See* Decision 7-8). Carter's showing was reasonable in view of Adair's reliance on PCT claims 8 and 16. Carter met its burden for relief and shifted the burden to Adair to either show why Carter's showing was insufficient or to direct us to another pre-critical date claim that was materially the same as the copied claim.

Adair argues our Decision was incorrect in stating that a presumption of a material difference was created since Adair's involved claim 24 was added and allowed only after the pre-critical date PCT claims were rejected and cancelled (Request at 6). However, when an applicant adds a limitation to a claim in response to a rejection and the added limitation results in allowance of the claims, the limitation is presumed to be necessary to patentability. *See Corbett, 568 F.2d at 765.; Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd,* 535 U.S. 722, 734 (2002).

Adair notes, for the first time in the Request, that pre-critical date claim 2 recites all the heavy chain residues of involved claim 24. (Request 6). "Arguments not raised

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[1] "FF" indicates the Findings of Fact provided in the Decision, which we incorporate into this Order.

in briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing except [as based on recent relevant Board of Federal Circuit decisions]." 37 C.F.R. § 41.52(a)(1). Thus, we decline to consider that pre-critical date claim 2 satisfies the requirements of 35 U.S.C. § 135(b)(1). Even if we were to consider claim 2 at this point, Adair has failed to provide a sufficient comparison to show that claim 2 is materially the same as the copied claim.

In our Decision, we noted that Adair, as an applicant, could have attempted to add an original pre-critical date claim to its application if it believed that such a claim is allowable and would interfere with the Carter claims. (Decision at 10). Adair argues that "it would clearly have been futile for Adair to attempt to add an original pre-critical date claim" because "as the Decision noted, the original pre-critical date claims were rejected and canceled." (Request 8). By not arguing for the patentability of the original pre-critical date claims it relied upon for support under section 135(b)(1), Adair's position is contrary to the policy stated in *Univ. of Cal.* "prevent[ing] a patent applicant from relying on the filing date of a claim to which it is not statutorily entitled." *Univ. of Cal.*, 455 F.3d at 1377.

III. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Adair's Request that we modify our Decision is DENIED.

ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
Administrative Patent Judge

/ss/ Sally C. Medley
SALLY C. MEDLEY
Administrative Patent Judge

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Appeal Nos. 2011-1212, -1213
(Interference No. 105,744)

United States Court of Appeals
for the
Federal Circuit

JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL
and JOHN SPENCER EMTAGE,

Appellants,

– v. –

PAUL J. CARTER and LEONARD G. PRESTA,

Cross Appellants.

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE,
BOARD OF PATENT APPEALS AND INTERFERENCES

BRIEF OF THE APPELLANTS JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL AND JOHN SPENCER EMTAGE

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May 13, 2011

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) APPELLANT ADAIR certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

UCB Pharma S.A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

UCB Pharma S.A. is wholly-owned by UCB S.A.
Financiere de Tubize S.A. is a publicly owned company that owns more than 10% of the stock of UCB S.A.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Cozen O'Connor P.C. – Doreen Yatko Trujillo, Michael B. Fein, Kyle Vos Strache

May 13, 2011
Date: May 13, 2011

Doreen Yatko Trujillo
Signature of counsel

Doreen Yatko Trujillo
Printed name of counsel

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STATEMENT OF RELATED CASES

No other appeal from the same interference was previously before this or any other appellate court. Another appeal of a final judgment of the Board of Patent Appeals and Interferences ("Board") in Interference 105,762 is before this Court. The Notice of Appeal was filed April 1, 2011. No other case is known to counsel to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

1. The statutory basis for jurisdiction of the Board for application to patent interferences is 35 U.S.C. § 135(a).

2. The statutory bases for jurisdiction of this Court to hear the appeal of a decision of the Board in an interference are 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141.

3. This appeal is from a final judgment of the Board dated September 2, 2010 (A19-21), which was affirmed in the "Order -- Decision on Adiar [sic] Request for Rehearing," dated November 5, 2010 (A22-28).

4. The appeal is timely, as the Notice of Appeal was filed by Express Mail on January 4, 2011 with the United States Patent & Trademark Office ("USPTO"). The USPTO confirmed timely filing with the submission of the Certified Index on February 14, 2011, and the case was docketed at this Court on February 15, 2011. *See,* 35 U.S.C. § 142.

STATEMENT OF THE ISSUE

Whether the Board erred as a matter of law in finding that Adair's single claim involved in Interference 105,744 was barred under 35 U.S.C. § 135(b)(1). In reaching this finding, the Board:

a) required that claims filed before the critical date ("pre-critical date claims") that are relied upon to support claims filed after the critical date ("post-critical date claims") for purposes of *section 135(b)(1)* be shown to be patentable;

b) created a material differences test between pre- and post-critical date claims without any reference to the patent claims being copied;

c) created a presumption of material differences when pre-critical date claims have been amended or canceled; and

d) improperly shifted the burden of production to Adair.

STATEMENT OF THE CASE

This is an appeal of a final judgment of the Board in an interference between Adair and Carter awarding judgment on priority of Count 1 ("Count"), the sole count in the interference, to Carter (A19-21). Carter is in the interference based upon U.S. Patent No. 6,407,213, filed November 17, 1993 and issued June 18, 2002 ("the Carter patent") (A97). Adair is in the interference based upon U.S. Application Serial No. 11/284,261, filed November 21, 2005 ("the Adair

application") (A97). The Board decided that Adair's only claim in interference was barred under 35 U.S.C. § 135(b)(1) (A11) and entered judgment against Adair on September 2, 2010 (A19-21). Adair requested rehearing of the Board's decision on October 1, 2010 (A426-35). The Board denied Adair's request on November 5, 2010 (A22-27).

STATEMENT OF THE FACTS

Count 1, the sole count of the interference, is reproduced below:

> A humanized antibody heavy chain variable domain comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind antigen incorporated into a human antibody variable domain, and further comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of: 24H, 71H, 73H, and 78H, utilizing the numbering system set forth in Kabat.

(A98). As the Board observed, the invention of the Count is drawn to humanized antibodies, that is, antibodies that are a combination of human and non-human regions (A3). More specifically, the invention of the Count is drawn to the variable domain of the heavy chain of humanized antibodies. Naturally occurring antibodies comprise two heavy chains and two light chains, each of which has a variable domain that is involved in binding the antibody to antigen (A49). Antibodies of non-human origin are naturally antigenic in humans when used in therapy and can give rise to an undesirable anti-antibody response (A561). Humanization techniques, typically involving the use of recombinant DNA

technology, were developed to make non-human antibodies less antigenic (A561-62). The humanized antibodies of the Carter claims, the Adair claim, and the Count have non-human Complementarity Determining Regions (CDR) and human Framework Regions (FR), with a specifically recited non-human substitution in the FR, i.e., at one of residues 24, 71, 73, or 78 in the amino acid sequence using the numbering system according to Kabat (A3; A98). Such antibodies are also known as CDR-grafted antibodies (A562-65).

A. Factual Background

The Patent Statute requires that claims that are to substantially the same invention as claims in an issued patent be made prior to one year from the date on which the patent was granted.

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

35 U.S.C. § 135(b)(1). The "critical date" for purposes of determining compliance with 35 U.S.C. § 135(b)(1) is, thus, June 18, 2003 (A4).

Adair requested this interference in a preliminary amendment filed concurrently with the filing of the Adair application on November 21, 2005 ("Preliminary Amendment"), which was after the critical date (A653-73). Although the rules do not require Adair to do so (*see* 37 C.F.R. § 41.202(a)), Adair

showed compliance with 35 U.S.C. § 135(b)(1) in the Preliminary Amendment (A656-58). Adair contended that claim 16 as depending from claim 8 of PCT/GB90/02017, filed December 21, 1990 ("the PCT application") was to substantially the same subject matter as claim 1 of the Carter patent (A656-58). The PCT application was filed almost 12 years before the Carter patent issued and well prior to one year from the date on which the Carter patent issued. Claims 8 and 16 of the PCT application are duplicated below:

> 8. A CDR-grafted antibody **light** chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, **58**, and 71.
>
> 16. A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(A748-49, emphasis added.) Claim 1 of the Carter patent is duplicated below:

> 1. A humanized antibody variable domain comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind an antigen incorporated into a human antibody variable domain, and further comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of: 4L, 38L, 43L, 44L, **58L**, 62L, 65L, 66L, 67L, 68L 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, and 92H, utilizing the numbering system set forth in Kabat.

(A91, emphasis added.) (The "L" or "H" after a number in claim 1 of the Carter patent refers to the light chain or heavy chain, respectively (A1374).) Both claim 8 of the PCT application and claim 1 of the Carter patent cover a CDR-grafted light chain variable region in which a single residue in the light chain, i.e., residue 58, is substituted.

In the Preliminary Amendment, Adair proposed that the count of the interference be claim 24 as submitted, or claim 30 or claim 80 of the Carter patent (A669-70). Claim 24 as submitted is duplicated below:

> 24. A humanised antibody **heavy** chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises an amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78, and combinations thereof, as numbered according to Kabat.

(A655, emphasis added.) As claim 1 of the Carter patent, claims 30 and 80 recite amino acid substitutions at residues in the framework of the heavy and light chains (A92-93).

Instead of adopting Adair's proposed count, the Board devised its own count, set forth above. Claims 30, 31, 60, 62, 63, 66, 67, 70, 73, and 77-81 of the Carter patent were designated as corresponding to the Count (A98). Claim 24 of the Adair application ("Adair claim 24") was designated as corresponding to the Count (A98). Adair claim 24 is duplicated below:

> A humanised antibody **comprising a** heavy chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises **a non-human** amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78, and combinations thereof, as numbered according to Kabat.

(A199, emphasis added.) Adair claim 24 differs from claim 24 submitted in the Preliminary Amendment by the language highlighted in bold above.

Over four years after Adair first attempted to provoke an interference, the present interference was declared (A95). In the declaration of the interference, Adair was accorded priority benefit, ultimately, of GB 8928874.0, filed on December 21, 1989 ("the Adair GB") (A99). Adair was also accorded priority benefit of, *inter alia*, a Patent Cooperation Treaty ("PCT") application, PCT/GB90/02017, filed December 21, 1990 ("the PCT application") (A99). Carter was accorded priority benefit of, ultimately, U.S. Application Serial No. 07/715,272, filed June 14, 1991 ("the Carter '272 application") (A99). Carter was, thus, designated the Junior Party in the interference (A96).

As the Junior Party in the interference, the burden would have been upon Carter to prove priority of invention by a preponderance of the evidence. 37 C.F.R. § 41.207(a)(2). Notably, Carter's earliest priority date, i.e., June 14, 1991, is almost six months after the PCT application filing date, i.e., December 21, 1990, and almost 18 months after the Adair GB filing date, i.e., December 21, 1989.

Therefore, it seems unlikely that Carter could establish a conception date earlier than December 21, 1989, much less show reasonable diligence from just before December 21, 1989 to June 14, 1991. Carter did not have to do so.

In its list of proposed motions, Carter proposed filing a motion that Adair claim 24 is barred under 35 U.S.C. § 135(b)(1) ("135(b) motion") and requested that the motion be treated as a threshold issue (A266). The Standing Order in place for this interference provides that preliminary motions may be decided prior to motions for priority (see A175-76). The rules of practice for interferences also provide that certain threshold issues may be decided before others. 37 C.F.R. § 41.201. One such threshold issue is repose under 35 U.S.C. § 135(b), for claims first made after issuance of the movant's patent. 37 C.F.R. § 41.201.

The Board authorized Carter to file its 135(b) motion prior to the other authorized motions (A272). Carter filed its 135(b) motion (Carter Substantive Motion 1) on May 28, 2010 (A294). The Board authorized Adair to file an opposition to the 135(b) motion, which it did on July 14, 2010 (A367). No reply by Carter was authorized.

B. Summary Of Carter's 135(b) Motion

Carter alleged that Adair must satisfy at least three conditions to comply with 35 U.S.C. § 135(b)(1): 1) Adair must have presented a pre-critical date claim that is patentable to Adair; 2) Adair must have presented a pre-critical date claim

that defines the same or substantially the same subject matter as a claim of the Carter patent; and 3) Adair claim 24 cannot differ in any material limitation from Adair's pre-critical date claims. Carter cited four cases allegedly supporting condition one above -- *Adang v. Umbeck,* 2007 U.S. App. LEXIS 25198 (Fed. Cir. 2007); *Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 927 (Fed. Cir. 2004); *PIN/NIP, Inc. v. Platte Chem. Co.,* 304 F.3d 1235, 1247-48 (Fed. Cir. 2002); and *In re Curtis,* 354 F.3d 1347, 1353-54 (Fed. Cir. 2004) (A304). Regarding condition two, Carter argued that Adair's original pre-critical date claims submitted in the PCT application were rejected as indefinite and that the Carter patent claims are not indefinite, so the two sets of claims *must* differ in ways having patentable significance (A304-05). Carter argued that many of the non-original pre-critical date claims were determined to be not patentable, without citing any support therefor or identifying which claims (A305). Carter also argued that such claims differ from the Carter patent claims in material limitations, asserting that Adair's non-original pre-critical date claims recite positions that all must be donor, whereas the Carter patent claims do not require that each recited position be donor (A307). Finally, regarding condition 3, Carter reiterated the arguments for conditions one and two, and also argued that Adair claim 24 regards the heavy chain, whereas claims 16 and 8 of the PCT application regarded the light

chain and that Adair claim 24 and **all** of Adair's pre-critical date claims were, thus, materially different from each other (A298).

C. Summary Of Adair's Opposition

Regarding Carter's condition one, Adair argued that none of the cases Carter cited to support its assertion that the pre-critical date claims must be patentable supported the assertion and that, as the Board has held previously, canceled claims can be relied upon to provoke an interfere (A369-70). Adair cited *Tezuka v. Wilson*, 224 USPQ 1030 (Bd. Pat. Int. 1984) in support (A370). Regarding condition two, Adair argued that Carter did not specify which material limitations were lacking and, therefore, failed to meet its burden on the issue (A370-71). Adair also argued that claim 16, as depending from claim 1 of the PCT application, effectively contains all limitations of claim 66 of the Carter patent (A371). Regarding condition three, Adair argued that Carter was misapplying the materiality test (A372-73). Adair argued that the test whether or not a limitation is material for purposes of § 135(b) is to be determined in view of the **patent** claims in interference and that all material limitations of the **patent** claims must be present in, or necessarily result from, the limitations of both Adair's pre-critical date and post critical-date claims (A372). *In re Berger*, 279 F.3d 975, 61 USPQ2d 1523 (Fed. Cir. 2002) and *Corbett v. Chisolm*, 568 F.2d 759, 765-766, 196 USPQ 337, 342 (CCPA 1977) were cited in support (A372).

D. Summary Of The Board's Decision

The Board asserted that Adair did not dispute that claims reciting a heavy chain and claims reciting a light chain differ materially (A8). The Board disagreed with Adair's argument that Carter was misapplying the materiality test, but then quoted a statement from *Regents of the Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371 (Fed. Cir. 2006), *reh'g en banc denied*, 2006 U.S. Appl. Lexis 27583 (Fed. Cir., Oct. 16, 2006) that seems to support Adair's interpretation instead of the Board's – i.e., that pre-critical date claims must provide support for post-critical date **identity** between the **involved claim** and the patentee's **patent** (A8, emphasis added). The Board argued that Adair's pre-critical date claims must be compared with its own claims for identity, not Carter's (A9).

The Board then considered original pre-critical date claims 1 and 16 of the PCT application as compared to Adair claim 24, without any reference to claim 66 of the Carter patent, and found that because claims 1 and 16 were rejected and ultimately canceled, they are materially different from Adair claim 24 (A9-10). The Board reached this conclusion by combining two distinct areas of case law – interference and doctrine of equivalents – to create a new presumption. The Board cited *Corbett,* 568 F.2d at 765, to show that one example of a material limitation is one that is necessary to patentability (A9). The Board relied upon *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002) for creating a

presumption that, when an applicant adds a limitation to a claim in response to a rejection which results in allowance of the claim, that limitation was necessary to patentability, i.e., material (A9). Although the Board had just created this presumption in its decision, it faulted Adair for not showing why the limitations that differ between Adair claim 24 and original claims 1 and 16 were **not** necessary to the patentability of Adair claim 24 and stated that Adair did not point to any other pre-critical date claim that is identical to or includes the same material limitations as Adair claim 24 (A10). The Board stated that Adair could have sought authorization to file a motion to add a pre-critical date claim that interferes with the Carter claims but did not (A10).

The Board cited *Regents*, 455 F.3d at 1376, for the proposition that the USPTO should declare an interference upon receipt of a claim that satisfies 35 U.S.C. § 135(b) and is otherwise patentable (A10). Although seemingly recognizing that the two issues are separate, the Board then alleged that patentability of pre-critical date claims is required to satisfy 35 U.S.C. § 135(b), based upon the following statement in *Regents*, at 1377, – "this court perceives no inequity in a construction of *section 135(b)(1)* that might, in some circumstances, prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled" (A10-11).

E. Summary Of Adair's Request For Rehearing

Adair challenged the applicability of *Regents* to the present facts because, in *Regents*, the pre-critical date claims were copied from the patent whereas Adair's post-critical date claims were copied from the patent (A428). As Adair also argued, *Regents* distinguished cases in which the post-critical date claims were copied (A428). Adair asserted that the proper test is that set forth in *Berger,* 279 F.3d 975 and *Corbett*, 568 F.2d 759, and is whether or not all material limitations of the copied patent claim are present in the pre-critical date claim (A428-29). Specifically, Adair cited the following passage from *Berger:*

> Because the prior art applies in like manner to the **claims as copied**, the materiality of a limitation in a **claim copied** to provoke an interference **translates** to the copying inventor's application for purposes of assessing compliance with **35 U.S.C. § 135(b)**.

Berger, 279 F.3d at 983 (emphasis added) (A428-29). Adair also cited the following passage from *Corbett*:

> [t]here being a material limitation of the **copied** [Chisholm patent] claim not present in Corbett's [pre-critical date] claims 24-27, they cannot be said to be directed to **substantially the same invention.**

Corbett, 568 F.2d at 766 (citation omitted) (emphasis added) (A429). Adair pointed out that neither the Board, nor Carter, had argued that Adair's pre-critical date claims do not contain all material limitations of the Carter patent claims (A429).

Adair further argued that the passage from *Regents* quoted by the Board is not inconsistent with Adair's interpretation regarding the materiality test (A429-30). Adair contended that, if, after prosecution, the applicant's allowed post-critical date claims lack limitations from the pre-critical date claims that were necessary to the patentability of the **patent** claims, that applicant should not be able to rely upon the pre-critical date claims to provoke an interference with that patent (A430). Under such circumstances, the allowable post-critical date claims are no longer to substantially the same invention as the patent claims as required by 35 U.S.C. § 135(b)(1) (A430).

Adair also argued that, even if the materiality test were to be applied as the Board asserted, i.e., without reference to the patent claims being copied, the Board made several errors. First, canceled claims can be relied upon for determining compliance with 35 U.S.C. § 135(b)(1) (A430). Second, the burden should have been placed on Carter, as the movant, to show that **all** of the pre-critical date claims differed materially from Adair claim 24, not on Adair to show that none of the pre-critical date claims differed materially from Adair claim 24 (A430-31). Third, an original pre-critical date claim, claim 2 of the PCT application, recites all the residues recited in Adair claim 24, as Adair showed in an attached chart (A431, A435). Finally, Adair observed that it would have been futile to attempt to add an original pre-critical date claim because Adair would have to certify that it was not

aware of any reason the claim it was adding is not patentable considering that the original pre-critical date claims had been rejected (A432-33).

F. Summary Of The Board's Decision On Rehearing

The Board repeated its quote from *Regents* that Adair contends actually supports Adair's interpretation of the material differences test (A24). The Board then argued that Adair did not point to support in *Berger* for its argument that "[m]ateriality is determined in view of the patent claims being copied" (A24), even though Adair had provided a quote and page citation from *Berger* as noted above. The Board said that it was reasonable for Carter to rely upon only those claims that Adair had relied upon in its Preliminary Amendment and that, by doing so, Carter met its burden for relief and shifted the burden to Adair to show why Carter's showing was insufficient or to direct the Board to another pre-critical date claim that was materially the same as the copied claim (A25). Notably, the Board did not argue that claim 2 of the PCT application differs materially from Adair claim 24 but, rather, declined to consider claim 2 as being submitted too late and said that, even if it did consider claim 2, Adair failed to provide a sufficient comparison to show that claim 2 is materially the same as the copied claim (A25-26), despite the fact that Adair had provided a chart comparing the two claims. Finally, the Board argued that Adair's failure to argue the patentability of the original pre-critical date claims is contrary to what it refers to as the "policy" stated in *Regents*, i.e.,

"prevent[ing] a patent applicant from relying on the filing date of a claim to which it is not statutorily entitled" (A26).

SUMMARY OF THE ARGUMENT

The policy of *section 135(b)* is to place a time limit on a patentee's exposure to interferences. *Regents*, 455 F.3d at 1376. Where an interference is merely belated, i.e., should have been declared earlier by the USPTO, the interference should not be barred by *section 135(b)(1)*. *Id.*, at 1376. As is clear from the foregoing facts, Adair was claiming substantially the same subject matter as Carter well before the Carter patent issued. The present interference should have been declared earlier.[1] Adair, thus, should not be barred under *section 135(b)(1)*. The Board, however, seems to have a different view.

The Board has interpreted *Regents* in a manner which Adair contends is inconsistent with the case to bar Adair under *section 135(b)(1)*. First, the Board has interpreted *Regents* to require that applicants relying upon pre-critical date claims show that those pre-critical date claims are patentable (A26). But such an interpretation is not only inconsistent with *Regents*, but it is also inconsistent with precedent that is binding on this Court. Second, the Board has interpreted *Regents*

[1] Per the Manual of Patent Examination and Procedure ("MPEP"), examiners are required to perform an interference search of the comprehensive inventive features of the broadest claim prior to issuance. MPEP, § 1302.08. Notably, at the time the Carter patent issued, the Assistant Examiner on the Carter patent was examining an application to which the Adair application claims priority (*see* A34 and A1235).

as requiring a new material differences test between an applicant's pre- and post-critical date claims without any reference to the patent claims being copied (A24). Adair contends that *Regents* did not create such a test.

The Board's incorrect interpretation of *Regents* enabled it, effectively, to shift the burden of persuasion to Adair regarding Carter's 135(b) motion in contravention of the rules and Standing Order. The Board created a presumption that pre-critical date claims that are amended for any reason are materially different from post-critical date claims in its decision and then faulted Adair for not acting in a manner consistent with the presumption in its papers, which were filed before the presumption was created (A9-10). Adair would have to be prescient to have done so.

Finally, the Board inappropriately shifted the burden of production to Adair in contravention of the rules and Standing Order. The Board found that Carter met its burden of going forward by only specifically addressing two of Adair's numerous pre-critical date claims because that is all Adair addressed in its paper attempting to provoke the interference (A25). But, Adair did not have to address any claims in its paper attempting to provoke the interference. 37 C.F.R. § 41.202(a). Rather, Carter, as the movant, was required to show that none of Adair's pre-critical date claims satisfied the requirements of *section 135(b)(1)*. 37 C.F.R. § 41.208(b). Because the Board inappropriately shifted the burden of

production to Adair, it refused to consider an original pre-critical date claim that Adair argued met the Board's new materiality test, since the argument was submitted in Adair's request for rehearing (A26).

ARGUMENT

I. Standard of Review

The Board's legal conclusions are reviewed without deference; the Board's factual findings are reviewed for substantial evidence. *Hitzeman v. Rutter*, 243 F.3d 1345, 1353-54 (Fed. Cir. 2001).

II. Analysis

The Board's construction of 35 U.S.C. § 135(b)(1) is a question of law. *Regents*, 455 F.3d at 1373. For the reasons set forth below, Adair contends that the Board erred as a matter of law in its construction of *section 135(b)(1)*. The Board imposed additional requirements for compliance with *section 135(b)(1)* not supported by the statute or the case law, created a presumption that did not exist prior to its decision in this interference, and improperly shifted the burden of going forward to Adair. It is only by doing so that the Board was able to find that Adair did not comply with *section 135(b)(1)*.

A. The Board Erred By Requiring That Pre-Critical Date Claims Be Patentable

The Board asserted that this Court stated a policy in *Regents* under *section 135(b)(1)* of "prevent[ing] a patent applicant from relying on the filing date of a claim to which it is not statutorily entitled" (A26). In view of this "policy," the Board imposed a requirement upon Adair to argue the patentability of original pre-critical date claims being relied upon for support under *section 135(b)(1)* (A10-11, A26). Indeed, the Board criticized Adair for not seeking authorization to file a motion to add a pre-critical date claim that interferes with the Carter claims to the interference (A26). In such a motion, Adair would have to argue the patentability of any claim it was trying to add to the interference. 37 C.F.R. § 41.208 (c)(1).

Contrary to what the Board asserted, this Court did not state that there is a policy requiring a showing of patentability of pre-critical date claims in *Regents*. Rather, this Court stated the following:

> To the contrary, this court perceives no inequity in a construction of *section 135(b)(1)* that *might, in some circumstances*, prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled.

Regents, 455 F.3d at 1377 (emphasis added). The Board cropped the foregoing quote in half and then characterized it as setting forth a policy, something this Court did not do.

Regardless, the statement does not say that the Court perceives no inequity in a construction that *would, in all circumstances*, prevent an applicant from relying on the filing date of a claim to which it was not statutorily entitled, as the Board intimates. As Adair argued, an equally appropriate interpretation of this statement is that if, after prosecution, the applicant's allowed post-critical date claims lack material limitations from the pre-critical date claims, i.e., limitations that were necessary to the patentability of the **patent** claims being copied, that applicant should not be able to rely upon the pre-critical date claims to provoke an interference with that patent (A430). Under such circumstances, the allowable post-critical date claims are no longer to substantially the same subject matter as the patent claims, as is required by 35 U.S.C. § 135(b)(1) (A430). Adair's interpretation is more consistent with the policy which was stated in *Regents* – i.e., to place a time limit on a patentee's exposure to an interference proceeding. *Regents*, 455 F.3d at 1376. Such is not the present case. No one has argued that allowable Adair claim 24 is not to substantially the same invention as a claim of the Carter patent.

Further, a requirement that the pre-critical date claims be patentable is contrary to legal precedent. This Court's predecessor court considered pre-critical date claims that had been canceled over 15 months after being introduced, and 27 months before the patent issued, for compliance with *section 135(b)(1)*. *Corbett*, 568 F.2d at 761, 765. The court in *Corbett* did not comment on the patentability of

the canceled claims, nor require that they not have been rejected. Further, *Corbett* specifically approved of combining pre-critical date claims to find support for all material limitations of the patented claims for compliance with *section 135(b)*, as long as the claims being combined were to the same invention. *Id.*, 568 F.2d at 766. If one can combine claims, then patentability of individual claims is surely not relevant.

This Court is bound by precedent of the Court of Customs and Patent Appeals. *South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982). Such precedent cannot be overruled by a panel of this Court. *Mothers Restaurant, Inc. v. Mama's Pizza, Inc.*, 723 F. 2d 1566, 1573 (Fed. Cir. 1983). *Regents* was a panel decision, and rehearing en banc was denied. *Regents*, 2006 U.S. Appl. Lexis 27583 (Fed. Cir., Oct. 16, 2006). Thus, even if the language in *Regents* relied upon by the Board could be interpreted to impose a requirement for patentability of pre-critical date claims, such a requirement would be inappropriate as contrary to binding precedent.

B. The Board Erred By Creating A New Material Differences Test

Section 135(b) requires that the claims being made to provoke an interference be to substantially the same subject matter as a claim of an issued patent. 35 U.S.C. § 135(b)(1). When the patent claims are copied post-critical date, as in the present case, the case law has allowed applicants trying to provoke an

interference to rely upon pre-critical date claims to show compliance with *section 135(b)(1)* as long as the pre-critical date claims contain all material limitations of the copied post-critical date claim. Materiality is to be determined in view of the patent claim being copied, as Adair has repeatedly argued (A372; A428-29). *See Berger*, 279 F.3d at 983; *Corbett*, 568 F.2d at 766.

Allegedly based upon *Berger* and *Regents*, the Board imposed a requirement that Adair's pre-critical date claims include all material limitations of the post-critical date claims, regardless of whether those limitations were material limitations of the patented claim (A24). To the extent *Regents* is found to have created such a requirement, Adair contends that *Regents* is not applicable to the present facts (A428). As noted above, Adair's **post**-critical date claims were copied from the patent. In *Regents*, the **pre**-critical date claims were copied from the patent. *Regents*, 455 F.3d at 1373. As Adair argued, *Regents* distinguished cases in which the post-critical date claims were copied from the patent (A428). *Id.*, at 1375 (distinguishing *In re Frey*, 182 F.2d 184 (CCPA 1950) and *Thompson v. Hamilton*, 152 F.2d 994 (CCPA 1946)).

Adair maintains, however, that *Regents* did not create a new test regarding materiality.[2] First, materiality was not at issue in *Regents* -- the appellant in

[2] In its initial decision on motions, the Board asserted that the new materiality test is the proper test to be applied (A9). In its decision on Adair's request for

Regents did not contest the Board's finding of material differences between the pre- and post-critical date claims, just whether or not the presence of material differences mattered. *Regents*, 455 F.3d at 1373. Second, as is clear from this Court's repeated reference to *section 135(b)(1)* throughout the opinion in *Regents*, and its distinguishing of cases in which the post-critical date claims were the ones that were copied, the reason the pre- and post-critical date claims are to be compared with one another is to ensure that the post-critical date claims are still to substantially the same subject matter as the **patent** claims. Finally, this Court said that the material differences test discussed in opinions like *Berger* is to be applied. *Id.*, at 1376. As noted above, the material differences test set forth in *Berger* is whether or not all material limitations of the patent claim are present. In *Berger*, a limitation in the copied claim that had been added by the patentee to avoid prior art was found to be material. *Berger*, 279 F.3d at 982.

> Because the prior art applies in like manner to the claims **as copied**, the materiality of a limitation in a claim **copied** to provoke an interference **translates** to the copying inventor's application for purposes of assessing compliance with 35 U.S.C. § 135(b).

Id., at 983 (emphasis added).

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rehearing, the Board asserted that the new materiality test is an additional requirement (A24). Adair contends that both assertions are wrong.

C. The Board Erred By Creating A Presumption That Any Differences Between Adair's Pre- and Post-critical Date Claims Are Material

Adair maintains that it does not need to show that its pre-critical date claims have all material limitations of its post-critical date claim without reference to the Carter patent claims. Nonetheless, in response to Carter's implication that claims to heavy chain (e.g., Adair claim 24) are different from claims to light chain (e.g., original claim 8 of the PCT application)(A298), Adair pointed out that original pre-critical date claim 1 of the PCT application recited heavy chain (A371). Claim 16 as depending upon claim 1 of the PCT application, thus, is to substantially the same invention as claim 66 of the Carter patent (A371). The Board did not challenge Adair's argument that original pre-critical date claim 16 as depending from claim 1 of the PCT application was to the same patentable subject matter as the Carter patent claims (A9). Rather, the Board said that it was not convinced that Adair had a pre-critical date claim that does not differ materially from Adair claim 24, noting that claims 1 and 16 of the PCT application had been rejected during prosecution and were canceled (A9).

Compounding the other two errors discussed above – i.e., requiring that the pre-critical date claims be patentable, and that there be no material differences between the pre- and post-critical date claims without reference to the patent claims being copied -- the Board created a presumption that a limitation added in response to a rejection that results in allowance is necessary to patentability and,

thus, material (A9-10). The Board created this presumption for the first time in its decision, and did so by combining two very divergent cases -- the *Corbett* and *Festo* cases discussed above (A9). As the Board acknowledged, however, *Festo* addresses infringement, i.e., the doctrine of equivalents, not interferences (A9). Adair contends that the combination of the two cases is, thus, inappropriate. Regardless, even in the context of the doctrine of equivalents, *Festo* does not create a presumption that a limitation was necessary to patentability. *Festo*, 535 U.S. at 734.

The patent rules provide that the burden of proof on a motion is on the movant. 37 C.F.R. § 41.208(b). The burden of proof for the 135(b) motion, thus, lay with Carter, not Adair. In view of their newly created presumption, the Board faulted Adair for not providing any reason why the limitations that differ between original pre-critical date claims 1 and 16 and Adair claim 24 were **not** material, for not pointing to another pre-critical date claim that is identical to or includes the **same** material limitations as Adair claim 24, and for not seeking authorization to file a motion to add a pre-critical date claim that interferes with the Carter claims (A10). The effect of the Board's fabricated presumption, thus, was to shift the burden of persuasion to Adair, particularly the requirement to move to resubmit a pre-critical date claim. As noted above, Adair would have to argue the patentability of such a claim. 37 C.F.R. § 41.208(c)(1).

D. The Board Erred By Shifting The Burden Of Production To Adair

Even assuming that the materiality test is as propounded by the Board, the burden was upon Carter to show that **all** of Adair's pre-critical date claims, i.e., those pursued during the more than 12-year period from December 21, 1990 through June 12, 2003, differed materially from Adair claim 24. 37 C.F.R. § 41.208(b) ("To be sufficient, a motion must provide a showing, supported with appropriate evidence, such that, if unrebutted, it would justify the relief sought. The burden of proof is on the movant."). Carter did not do so. Instead, Carter only specifically addressed the two claims Adair raised in its Preliminary Amendment to provoke the interference, and made sweeping conclusory statements regarding all others (A298; A308; A324). Carter had not specifically compared any other pre-critical date claims to Adair claim 24, in contravention of both the rules and the Standing Order (A430-31).

In its request for rehearing, Adair argued that Carter had not met its burden on the 135(b) motion and that, because of Carter's failure to meet its burden, the Board overlooked that claim 2 of the PCT application recites all residues recited in Adair claim 24 (A430-31). The Board responded that Carter's showing was reasonable in view of Adair's reliance on the two claims in its Preliminary Amendment (A25). Further, the Board said that the showing was sufficient to shift the burden to Adair to either show why Carter's showing was insufficient or to

direct the Board to another pre-critical date claim that was materially the same as the copied claim (A25). Consequently, the Board treated Adair's arguments regarding claim 2 of the PCT application as an untimely submission under 37 C.F.R. § 41.52(a)(1) and declined to consider whether the claim satisfied the requirements of *section 135(b)(1)* (A25-26). Thirty-seven C.F.R. § 41.52(a)(1), however, applies to *ex parte* appeals, not interferences (copy attached in Addendum).

Regardless, the Board erred in finding that Carter's showing was sufficient to shift the burden of production to Adair. Contrary to what the Board alleges, Carter's showing was not reasonable. The rules do not require that applicants wishing to provoke an interference show compliance with 35 U.S.C. § 135(b)(1). *See* 37 C.F.R. § 41.202(a). Adair, thus, did not have to argue that **any** pre-critical date claims were not materially different from Adair claim 24 to provoke the interference. In an abundance of caution, however, Adair argued that at least one of its pre-critical date claims -- claim 16 as depending from claim 8 of the PCT application -- was to substantially the subject matter as the Carter patent claims (A656-58). Adair evidently did so to its detriment. The Board should have denied Carter's motion outright. Instead, it shifted the burden of production to Adair.

Seemingly recognizing that its burden shifting was inappropriate, the Board alleged that, even if it were to consider claim 2 of the PCT application at this point,

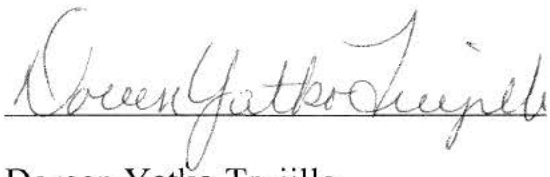
Adair had failed to provide a sufficient comparison to show that it is materially the same as the copied claim (A26). Adair is not sure what more it could have done. Adair argued that claim 2 of the PCT application recited all the residues recited in Adair claim 24, and included a chart in the appendix to its request for rehearing showing the same in bolded text (A431; A435). The chart included claims 1 and 16 of the PCT application, thereby showing that **all** limitations of Adair claim 24 were found in the pre-critical date claims (A435). Had the Board considered claim 2 of the PCT application, Adair would have prevailed even under the Board's erroneous analysis.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Adair contends that the Board erred as a matter of law in finding that Adair did not comply with 35 U.S.C. § 135(b)(1). Adair respectfully requests that this Court reverse the Board's decision and deny Carter Substantive Motion 1.

Respectfully Submitted,

Dated: May 13, 2011



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Filed August 30, 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261).

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY, *Administrative Patent Judges*

LANE, *Administrative Patent Judge*

ORDER - DECISION ON MOTIONS

I. STATEMENT OF THE CASE

The interference is before a panel for consideration of non-priority motions filed by Carter. No oral argument was held.

The Interference

Parties

The Interference involves junior party Carter and senior party Adair.

Junior party Carter is involved on the basis of its patent 6,407,213 ("the Carter '213 patent"), which issued 18 June 2002, from application no. 08/146,206, filed 17 November 1993. (Paper 1 at 3.) Claims 30, 31, 60, 62, 63, 66, 67, 70, 73, and 77-81 were designated as corresponding to the Count, while claims 1-29, 32-59, 61, 64, 65 68, 69, 71, 72, 74-76, and 82 were not. (Paper 1 at 4.)

The real party-in-interest of Carter is Genentech, Inc. (Paper 10).

Senior party Adair is involved on the basis of its application 11/284,261 ("Adair '261 application"), filed 21 November 2005. (Paper 1 at 3.) Claim 24, Adair's only pending claim, was designated as corresponding to the Count. (Paper 1 at 4.)

Adair was accorded priority benefit as to the Count of 08/846,658, filed 01 May 1997; 08/303,569, filed 07 September 1994, issued as 5,859,205 on 12 January 1999; 07/743,329, filed on 17 September 1991 ("the Adair '329 application"); PCT/GB90/02017, filed 21 December 1990 ("the Adair PCT application"); and GB 8928874.0, filed 21 December 1989. (Paper 1 at 5.)

The real party-in-interest of Adair is UCB Pharma, S.A. (Paper 4.)

Subject Matter

The parties' claims are drawn to an antibody that has been "humanized," that is, it has a combination of human and non-human regions and specific amino acids. Humanization allows antibodies to be raised, in the laboratory, in non-human animals (for example, mice) against antigens of interest and then changed so that they appear to the patient's body as if they were human antibodies. Humanized antibodies are beneficial because they do not raise dangerous anti-immunoglobulin responses in human patients, as non-human antibodies can. (Carter patent col. 1, l. 52, through col. 3, l. 8.) The humanized antibody of the involved Carter and Adair claims and the Count are antibodies that have a non-human Complementarity Determining Region ("CDR"), that is the region that binds antigen, and specifically recited non-human substitutions in other regions, called the Framework Regions ("FR"), of the antibody.

II. MOTIONS

Carter filed two substantive motions, which assert "threshold" issues that end the interference if the relief requested is granted. Carter Substantive Motion 1 ("Carter Motion 1") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 135(b)(1). Carter Substantive Motion 2 ("Carter Motion 2") requests that Adair claim 24 be found unpatentable under 35 U.S.C. § 112, first paragraph, for a lack of written description in the specification. As the moving party, Carter has the burden to show that it is entitled to the relief requested in its motions. Bd. R. 208(b).

A. CARTER MOTION 1

Findings of Fact

1. The involved Carter '213 patent issued 18 June 2002. (Carter Ex. 2001; Carter involved '231 patent.)

2. The "critical date," under 35 U.S.C. § 135(b)(1), by which Adair must have filed claims drawn to the same or substantially the same subject matter as the claims of the Carter '213 patent is 18 June 2003.

3. Adair filed the involved Adair '261 application on 21 November 2005, after the critical date. (Ex. 2002, Utility Patent Application Transmittal for Application 11/284,261.)

4. Claim 24, the only claim pending in the Adair '261 application was filed well after the critical date.

5. Claim 24 of the involved Adair '261 application recites:

> A humanised antibody comprising a heavy chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78, and combinations thereof, as numbered according to Kabat.

(Paper 5.)

6. None of the claims of the Adair PCT application or the Adair '329 application are identical to claim 24 of the involved Adair '261 application. (Adair response to Carter MF 42; citing Exs. 2005-2010, 2012-2022, 2024-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opposition 1 at 21 ("Adair Opp. 1")), but no claims identical to claim 24 of the involved Adair '261 application identified by

Adair.)

7. In its request for interference, Bd. R. 202, Adair identified claims 8 and 16 of the Adair PCT application as a basis for compliance with 35 USC §135(b).

(Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

8. Claim 8 of the Adair PCT and '261 applications recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(Ex. 2005, p. 68 and Ex. 2006, p. 68.)

9. Claim 16 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(Ex. 2005, p. 69 and Ex. 2006, p. 69.)

10. Claim 1 of the Adair PCT and '329 applications recites:

> A CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2005, p. 67 and Ex. 2006, p. 67.)

Analysis

35 U.S.C. § 135(b)(1) states that:

> [a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

Claim 24 of Adair's involved application, which corresponds to the Count, was filed more than one year from the date on which Carter's involved patent was issued. Because of the date Adair claim 24 was filed (*see* FF 4), it is, on its face, barred under 35 USC §135(b).

The bar of 35 USC §135(b) might be avoided if Adair had filed a claim that does not differ materially from claim 24. Indeed, in its request for interference, Bd. R. 202, Adair pointed to claims 8 and 16 of its pre-critical date application to support its assertion that claim 24 is not barred under the statute. (FF 7; Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5.)

"To establish entitlement to the earlier effective date of existing claims for purposes of the one-year bar of 35 U.S.C. § 135(b), a party must show that the later filed claim does not differ from an earlier claim in any 'material limitation,'" *In re Berger*, 279 F.3d 975, 981-82 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765-66 (CCPA 1977)). *See also Regents of Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371, 1375 (Fed. Cir. 2006) ("When a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for section 135(b)(1), [the Federal Circuit] applies the material differences test discussed in opinions like *Berger* to determine if

'such a claim' is barred."). The addition of a limitation for the purpose of making a claim patentable is strong evidence that the limitation is a material one. *See Corbett*, 568 F.2d at 765 (where a party's claim lacked a method step, the court noted that the party did "not seriously contend that this [was] not a material limitation, that [was] necessary to patentability . . . ."); *see also Wetmore v. Miller*, 477 F.2d 960, 964 (CCPA 1973) ("the 'fusible' limitation of appellant's claims must be regarded as not necessary to patentability and not 'material' for present purposes [of complying with 35 U.S.C. § 135(b)]").

Carter argues that the pre-critical date claims of Adair include different material limitations than those in Adair's involved claim 24. (Carter Motion 1 at 3.)

Claim 8 of the Adair PCT application, which is identical to claim 8 of the Adair '329 application, recites:

> A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 46, 48, 58 and 71.

(FF 8; Ex. 2005, p. 68; Ex. 2006, p. 68.) Claim 16 of the Adair PCT application, which is identical to claim 16 of the Adair '329 application, recites:

> A CDR-grafted antibody heavy or light chain or molecule according to anyone of the preceding claims comprising human acceptor residues and non-human donor residues.

(FF 9; Ex. 2005, p. 69; Ex. 2006, p. 69.) Thus, the claims that Adair relied upon for avoiding the 35 U.S.C. § 135(b) bar are drawn to a CDR-grafted light chain. Adair's involved claim 24, though, is drawn to a "humanized antibody comprising a heavy chain variable domain . . . ." (FF 5, Paper 5.) Involved claim 24 differs from original claims 8

and 16, by reciting a heavy chain variable domain instead of a light chain variable domain.

Adair does not dispute that claims reciting a heavy chain and claims reciting a light chain differ materially. Instead, Adair argues that Carter applied the incorrect standard for assessing whether a post-critical date claim differs materially from an earlier claim. According to Adair, the correct inquiry is whether Adair added or removed claim limitations after the critical date that were necessary to the patentability of *Carter's* claims, not Adair's own pre-critical date claims (Adair Opp. 1 at 6).

We disagree. A party seeking support from pre-critical date claims for interfering claims filed beyond the one-year bar of 35 U.S.C. § 135(b)(1) "must demonstrate that claims in [the pre-critical date] application provide pre-critical date support for the post-critical date identity between [the involved claim] and the [patentee's patent]. That demonstration necessarily entails a comparison between pre- and post-critical date claims." *Regents of Univ. of Cal.*, 455 F.3d at 1375.

Adair also argues, in response to Carter's assertion of the material differences between claims to heavy and light chains, that in addition to its claims drawn to light chains, Adair filed claims drawn to heavy chains before the critical date. Specifically, Adair cites claim 1 of its PCT application as claiming a CDR-grafted antibody heavy chain, and argues that it, together with claim 16, effectively contain all of the limitations of involved claim 66 of the Carter '213 patent. (Adair Opp. 1 at 5; *see* FF 10; Ex. 2005, p. 67; Ex. 2006, p. 67.).[1]

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1 Similarly in its showing under Bd. R. 202, Adair compared its pre-critical date claims to a Carter claim but not the current Adair claim. (Ex. 2003, Adair's Preliminary Amendment and Request for

Adair has not made the correct comparison. Under the guidance provided in *Regents of University of California,* Adair's pre-critical date claims must be compared with its own current claims, not Carter's. Thus we are not persuaded by Adair's argument that it is sufficient that it had on file a claim or claims that effectively contain the limitations of an involved Carter claim.

Even when we consider claims 1 and 16 of the PCT application as they compare to Adair's current claim (and not Carter claim 66 as Adair argues), we are not convinced that Adair had a pre-critical date claim that does not differ materially from its current claim. As Carter notes, (1) claims 1 and 16 of Adair's PCT application were rejected under several statutory grounds in the Adair '329 application, including 35 U.S.C. §§ 101, 112, first and second paragraphs, 102(b), and 103(a), (*see* Ex. 2038, Office Action mailed 18 November 1992), and (2) Adair then cancelled the claims and added new ones that were eventually allowed (Ex. 2007, Amendment of 19 January 1993, p. 2). (*See* Carter Motion 1 at 5-6.)

One example of a material limitation is one that is "necessary to patentability." *See Corbett*, 568 F.2d at 765. When an applicant adds a limitation to a claim in response to a rejection and the added limitation results in allowance of the claim, the limitation is presumed to be necessary to patentability. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 734 (2002) (in the context of applying the doctrine of equivalents, "[a] rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession

---

Interference under 37 C.F.R. § 42.202, p. 5.)

that the invention as patented does not reach as far as the original claim."); *see Berger*, 279 F.3d at 982 ("Inclusion of a limitation in a claim to avoid the prior art provides strong evidence of the materiality of the included limitation."). Adair does not provide any reason why the limitations that differ between involved claim 24 and original claims 1 and 16 were not necessary to the patentability of claim 24. Nor does Adair point to any other pre-critical date claim that is identical to or includes the same material limitations as its involved claim 24. (FF 6; *see* Carter MF 42, citing Exs. 2005-2010, 2013-2022, 2025-2027, 2029, and 2031-2035; not admitted or denied by Adair (Adair Opp. 1 at 21), but no claims identical to claim 24 of the involved Adair '261 application identified by Adair). We also note that as an applicant Adair could have, but did not, seek authorization to file a motion to add to its application a pre-critical date claim that interferes with the Carter claims (See Papers 23 and 73 (Orders setting times)).

Adair questions how one can provoke an interference if any claim amendments were made during prosecution under the standard stated in *Regents of University of California.* (Adair Opp. 1 at 7.) As explained in that case, "section 135(b)(1) [is] a statute of repose, placing a time limit on a patentee's exposure to an interference proceeding. *Regents Univ. of Cal.*, 455 F.3d at 1376. Despite this statute of repose, a "belated interference", i.e., based on a post-critical date claim, is appropriate in certain instances since "[t]he PTO should declare a valid interference upon receipt of a claim that satisfies section 135(b)(1), and which is otherwise patentable." (*Id.* at 1376). To insure that applicant did indeed timely present a patentable interfering claim, the post-critical date claim in interference must be materially the same as the claim that was timely presented. An applicant cannot expect to avoid the bar of §135(b) by timely

copying a claim from an issued patent when that claim is not patentable to that applicant. As the court noted, it "perceives no inequity in a construction of section 135(b)(1) that might, in some circumstances, prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled." (*Id.* at 1377).

We grant Carter Motion 1 and conclude that Adair involved claim 24 is barred under 35 U.S.C. § 135(b)(1).

B. CARTER MOTION 2

Carter asserts that claim 24 of Adair's involved application is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description support.

Findings of Fact

11. Adair's specification provides a "preferred protocol" to determine which residues of a human heavy chain should be substituted for donor residues, as follows

> 2. Heavy Chain
>
> 2.1 Choose donor residues at all of positions 23, 24, 49, 71, 73 and 78 of the heavy chain or all of positions 23, 24 and 49 (71, 73 and 78 are always either all donor or all acceptor).
>
> 2.2 Check that the following have the same amino acid in donor and acceptor sequences, and if not preferably choose the donor: 2, 4, 6, 25, 36, 37, 39, 47, 48, 93, 94, 103, 104, 106 and 107.

(Ex. 2002, pp. 17-18; MF 13.)

12. Adair's specification includes the following directions regarding substituting residues of a human heavy chain for donor residues:

> "Key residues" near the surface of the heavy chain, are residues 23, 71 and 73, with residues 1, 3, and 76 reported to contribute to a lesser extent. (Ex. 2002, p. 20; MF 16.)

"Key residues" among the "[p]acking residues" near the CDRs as 24, 49, and 78. (Ex. 2002, p. 21; MF 17.)

Example 1 reports that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78." (Ex. 2002, p. 52; MF 19.)

Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 only was found to be important for antigen binding. (Ex. 2002, pp. 57-58; MF 56.)

13. Adair's specification provides the following written description of a CDR-grafted antibody heavy chain with specified donor residues:

> Accordingly, in a first aspect the invention provides a CDR-grafted antibody heavy chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91.

(Ex. 2002 at p. 6.)

14. Adair's specification also provides the following written description of a CDR- grafted antibody heavy chain with specified donor residues:

> In preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues.

(Ex. 2002 at p. 7.)

15. Adair's specification states:

> A preferred protocol for obtaining CDR-grafted antibody heavy and light chains in accordance with the present invention is set out below together with the rationale by which we have derived this protocol. This protocol. and rationale are given without prejudice to the generality of the invention as hereinbefore described and defined.

(Ex. 2002, p. 16; MF 53.)

Analysis

The test for written description under 35 U.S.C. § 112, first paragraph, "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc., v. Eli Lilly & Co.*, 598 F3d 1336, 1351 (Fed. Cir. 2010). This analysis must consider the understandings of those in the art at the time of filing, *see Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125-26 (Fed. Cir. 2004), and must consider the specification as a whole, *see In re Wright,* 866 F.2d 422, 424-25 (Fed. Cir. 1989).

Claim 24 recites a humanized antibody with a heavy chain "compris[ing] a non-human amino acid substitution at a residue selected from the group consisting of 23, 24, 49, 71, 73, and 78 and combinations thereof . . . ." (FF 5; Paper 5). As Carter asserts, the broadest reasonable interpretation of this language in claim 24 encompasses a human heavy chain with residue substitutions at any number of the six residues recited, for example at only one residue, at all six residues, or at any combination in between. (*See* Carter Motion 2 at 1 and 5-6.)

Specification

In support of its argument that Adair's specification does not provide written description support of *any* of the six residues in claim 24, Carter cites to a "preferred protocol" provided in Adair's specification. Carter asserts that this protocol limits the invention to a human heavy chain framework region with either all of residues 23, 24, and 49, or all of residues 23, 24, 29, 71, 73, and 78, but not any of the residues individually. (Carter Motion 2 at 2 and 8; FF 11; Ex. 2002, Adair Specification, pp. 17-

18.) While this portion of the Adair specification appears to exclude many of combinations of substitutions encompassed by claim 24, other portions of Adair's specification are not so limiting.

For example, elsewhere Adair's specification provides that some "key residues" for making humanized antibodies are 23, 71 and 73, while other "key residues" are 24, 49, and 78. (FF 12; Ex. 2002, pp. 20 and 21; *see* Carter Motion 2 at 3.) Carter does not point to language in this part of the specification that indicates residues 23, 24, and 49 must *all* be substituted together or that 23, 24, 49, 71, 73, and 78 must *all* be substituted together.

In addition, while Carter cites Example 1 as reporting that "it is important to retain mouse residues at all of positions 6, 23, 24, 48 and 49, and possibly for maximum binding affinity at 71, 73 and 78" (FF 12: Ex. 2002, p. 52; *see* Carter Motion 2 at 3), Example 3 reports results wherein the crystal structure of the antibody heavy chain revealed that substitution at position 73 *only* was important for antigen binding. (FF 12; Ex. 2002, pp. 57-58; *see* Adair Opposition 2 at 3-4 ("Adair Opp. 2").) Thus, not all of the examples in Adair's specification support Carter's argument of a requirement for substation of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78.

Carter points to the Summary of the Invention section of Adair's application, which provides that human residues of the heavy chain can be substituted for donor residues at "at least one of positions 6, 23 and/or 24, 48 and/or 49, 71 and/or 73, 75 and/or 76 and/or 78 and 88 and/or 91." (Carter Motion 2 at 6; FF 13; Ex. 2002, p. 6.) According to Carter, this language does not provide written description because it is "ambiguous." (Carter Motion 2 at 6-8.) As evidence, Carter points to the rejection

under 35 U.S.C. § 112, second paragraph, of original claim 1 in the Adair '329 application, which contained this language from the Adair specification, and Adair's response canceling claim 1. (Carter Motion 2, MFs 22 and 25; Ex. 2007, p. 29-32; Ex. 2038, p. 6.)

We do not agree that the rejection under the second paragraph of § 112 necessarily shows a lack of written description support under the first paragraph of § 112. Carter's analysis lacks a consideration of the entire Adair specification and instead focuses only upon an isolated portion.

Carter points to another part of the Summary of the Invention, wherein "[i]n preferred embodiments, the heavy chain framework comprises donor residues at positions 23, 24, 49, 71, 73 and 78 or at positions 23, 24 and 49. The residues at positions 71, 73 and 78 of the heavy chain framework are preferably either all acceptor or all donor residues." (FF 14; Ex. 2002 at p. 7; *see* Carter Motion 2 at 8.) Carter characterizes this portion as providing that 71, 73, and 78 "must" be either all acceptor or all donor residues (Carter Motion 2 at 8), but the passage expressly states that positions 71, 73, and 78 are "preferably" all donor or all acceptor. Thus, this portion of Adair's specification is not as limited as Carter asserts.

It does not appear to us that, on its face, the Adair specification contains a requirement for substitution of *all* residues 23, 24, and 49 or *all* of residues 23, 24, 49, 71, 73, and 78. Carter does not direct us to the testimony or other evidence showing what the Adair specification would have conveyed to those skilled in the art at the time of filing such that we might find otherwise. "Argument of counsel cannot take the place of evidence lacking in the record." *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA

1977).

Prosecution History

Carter also points to the prosecution of Adair's applications as evidence that claim 24 is not supported by the Adair specification. According to Carter, Adair relied on the "preferred protocol" to distinguish claims of the Adair '329 application over the prior art and to overcome rejections for lack of enablement. (Carter Motion 2 at 9-13). The rejections, amendments, and arguments relied upon by Carter were not directed to involved claim 24 and Carter does not provide a detailed analysis of the claims that were being prosecuted and their relationship to Adair's current claim 24. Thus it is difficult to understand the relevance of the rejection of these claims to involved claim 24. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250, n.2 (Fed. Cir. 2008) ("Judges are not like pigs, hunting for truffles buried in briefs." (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991)).

In addition, though Carter notes instances when Adair discussed the "preferred protocol" and other rules for determining which residues to substitute, Carter does not point to instances where Adair argues that these are the *only* disclosures in their specification. In fact, other portions of the specification indicate that this "preferred protocol" is not limiting on the invention. (*See* Adair Opp. 2 at 3-4; FFs 15 and 16; Ex. 2002, Adair Specification, pp. 16 and 64.)

Carter has not shown that Adair claim 24 lacks sufficient written description support.

III. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Carter Motion 1 for judgment that Adair claim 24 is barred under 35 U.S.C. § 135(b) is GRANTED; and

FURTHER ORDERED that Carter Motion 2 for judgment that Adair claim 24 lacks written description support is DENIED; and

FURTHER ORDERED that judgment will be entered against Adair in a separate paper.

/ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
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/ss/ Sally C. Medley
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Paper 81

Filed 2 September 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTIA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILGEET SINGH ATHWAL,.
and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY C. MEDLEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

Judgment– Merits – Bd. R. 127

The Carter motion for judgment on the basis that the single involved Adair claim is barred under 35 U.S.C. § 135(b) was granted. (Paper 80). Because Adair no longer has an interfering claim that is not barred under 35 U.S.C. §135(b) it is appropriate to

enter judgment against Adair. *Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002).

It is

ORDERED that judgment on priority as to Count 1 (Paper 1 at 4), the sole count of the interference, is entered against senior party Adair;

FURTHER ORDERED that claim 24 of Adair application 11/284,261, which claim corresponds to Count 1 (Paper 1 at 4), is FINALLY REFUSED, 35 U.S.C. §135(a):

FURTHER ORDERED that if there is a settlement agreement, the parties are directed to 35 U.S.C. 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of the Carter involved patent and application and the Adair involved application.

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Paper 84
Filed: 5 November 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAUL J. **CARTER** AND LEONARD G. PRESTIA
Junior Party
(Patent 6,407,213),

v.

JOHN ROBERT **ADAIR**, DILGEET SINGH ATHWAL, and JOHN SPENCER EMTAGE
Senior Party
(Application No. 11/284,261),

Patent Interference No. 105,744
(Technology Center 1600)

Before SALLY GARDNER LANE, RICHARD TORCZON, and SALLY MEDLEY,
Administrative Patent Judges

LANE, *Administrative Patent Judge*

ORDER - DECISION ON ADIAR REQUEST FOR REHEARING

I. STATEMENT OF THE CASE

Adair filed a Request for Rehearing (Paper 83) ("Request") of our Order – Decision on Motions (Paper 80) ("Decision") granting Carter Substantive Motion 1. We considered the Request but do not modify our Decision.

II. ANALYSIS

Adair argues that we inappropriately relied on *Regents of Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371 (Fed. Cir. 2006), as the standard for determining whether Adair's involved claim 24 is barred under 35 U.S.C. § 135(b)(1). (Request 2). Adair attempts to distinguish the facts of *Univ. of Cal.* from the facts of the current interference, by noting that in *Univ. of Cal.* the claim in question was copied prior to the *pre*-critical date (and then later amended), while in the current interference the claim was copied only *after* the critical date. (Request 3). According to Adair, *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002), and *Corbett v. Chisholm*, 568 F.2d759 (CCPA 1977) are instructive under the current facts, instead of *Univ. of Cal.*

We disagree. *Univ. of Cal.* expressly denies that there is any difference under 35 U.S.C. § 135(b)(1) between a pre-critical date request for interference (where the copied claim would have been filed before the critical date) and a post-critical date request for interference (where the copied claim would have been filed after the critical date). *See Univ. of Cal.*, 455 F.3d at 1375 ("Section 135(b)(1) does not include any language suggesting that a pre-critical date request for interference makes any difference. Section 135(b)(1) bars any claim having a degree of identity with a claim in an issued patent unless such a claim is filed before the critical date. Thus, title 35 in this section does not demand notice of an impending interference, but instead prohibits

unsupported, post-critical date identity."); *see also id.* at 1374 ("this court does not perceive any legally significant distinctions between this case and [*Berger*]."). Thus, we did not err by relying on *Univ. of Cal.*

According to Adair, the only requirement under § 135(b)(1) is that the limitations of the copied patent claim are present in a pre-critical date claim. (Request 3-4). Both *Univ. of Cal.* and *Berger* explain that

> a copied claim may be entitled to the earlier effective date of prior claims in an application only if the copied claim does not differ from the prior claims in any material limitation. . . . The analysis focuses on the copied claim to determine whether all material limitations of the copied claim necessarily occur in the prior claims.

Berger, 279 F.3d at 982; *see also Univ. of Cal.*, 455 F.3d at 1375 (an applicant "must demonstrate that claims in [the pre-critical date] application provide pre-critical date support for the post-critical date identity between [the involved claim] and the [patentee's patent]. That demonstration necessarily entails a comparison between pre- and post-critical date claims."). We agree with Adair's statement that "the *Berger* test compares the pre-critical date claims and the post-critical date claims, which were copied from the patent, to ensure that all material limitations of the post-critical date claims are present in the pre-critical date claims" (Request 4). However, Adair has not pointed to support in *Berger* for its argument that "[m]ateriality is determined in view of the patent claims being copied" (*id.*). Even if Adair's claims do satisfy such a test for materiality, these claims must also satisfy the separate *Berger* and *University of California* requirements. *Berger* and *Univ. of Cal.* require that Adair's pre-critical date claims include all of the material limitations of its post-critical date claims to fulfill the requirement of 35 U.S.C. § 135(b)(1).

Adair also argues that we erred by not putting the burden on Carter to show that Adair's pre-critical date claims differ materially from its post-critical date claims. (Request 5-6). However, in its Motion (Paper 71), Carter showed that claim 24 (the copied claim) differs materially from those claims relied upon by Adair to meet the requirements of 35 U.S.C. § 135(b)(1), PCT claims 8 and 16 (*see* FF[1] 7, Ex. 2003, Adair's Preliminary Amendment and Request for Interference under 37 C.F.R. § 42.202, p. 5). PCT claims 8 and 16 were directed to a CDR-grafted antibody light chain, while Adair's involved claim 24 is directed to an antibody heavy chain variable domain. (*See* Decision 7-8). Carter's showing was reasonable in view of Adair's reliance on PCT claims 8 and 16. Carter met its burden for relief and shifted the burden to Adair to either show why Carter's showing was insufficient or to direct us to another pre-critical date claim that was materially the same as the copied claim.

Adair argues our Decision was incorrect in stating that a presumption of a material difference was created since Adair's involved claim 24 was added and allowed only after the pre-critical date PCT claims were rejected and cancelled (Request at 6). However, when an applicant adds a limitation to a claim in response to a rejection and the added limitation results in allowance of the claims, the limitation is presumed to be necessary to patentability. *See Corbett, 568 F.2d at 765.; Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd,* 535 U.S. 722, 734 (2002).

Adair notes, for the first time in the Request, that pre-critical date claim 2 recites all the heavy chain residues of involved claim 24. (Request 6). "Arguments not raised

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[1] "FF" indicates the Findings of Fact provided in the Decision, which we incorporate into this Order.

in briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing except [as based on recent relevant Board of Federal Circuit decisions]." 37 C.F.R. § 41.52(a)(1). Thus, we decline to consider that pre-critical date claim 2 satisfies the requirements of 35 U.S.C. § 135(b)(1). Even if we were to consider claim 2 at this point, Adair has failed to provide a sufficient comparison to show that claim 2 is materially the same as the copied claim.

In our Decision, we noted that Adair, as an applicant, could have attempted to add an original pre-critical date claim to its application if it believed that such a claim is allowable and would interfere with the Carter claims. (Decision at 10). Adair argues that "it would clearly have been futile for Adair to attempt to add an original pre-critical date claim" because "as the Decision noted, the original pre-critical date claims were rejected and canceled." (Request 8). By not arguing for the patentability of the original pre-critical date claims it relied upon for support under section 135(b)(1), Adair's position is contrary to the policy stated in *Univ. of Cal.* "prevent[ing] a patent applicant from relying on the filing date of a claim to which it is not statutorily entitled." *Univ. of Cal.*, 455 F.3d at 1377.

III. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Adair's Request that we modify our Decision is DENIED.

ss/ Sally Gardner Lane
SALLY GARDNER LANE
Administrative Patent Judge

/ss/ Richard Torczon
RICHARD TORCZON
Administrative Patent Judge

/ss/ Sally C. Medley
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Code of Federal Regulations

37

Revised as of July 1, 2010

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As of July 1, 2010

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whole or in part. Affirmance of a rejection of a claim constitutes a general affirmance of the decision of the examiner on that claim, except as to any rejection specifically reversed.

(b) *Remand.* The Board may remand an application to the examiner. If in response to a remand for further consideration of a rejection, the examiner enters an examiner's answer, within two months the appellant shall exercise one of the following two options to avoid abandonment of the application or termination of a reexamination proceeding:

(1) *Request to reopen prosecution.* Request that prosecution be reopened before the examiner by filing a reply under §1.111 of this title with or without amendment or submission of evidence. Any amendment or evidence must be responsive to the remand or issues discussed in the examiner's answer. A request that complies with this paragraph will be entered and the application or patent under reexamination will be reconsidered by the examiner under the provisions of §1.112 of this title. A request under this paragraph will be treated as a request to dismiss the appeal.

(2) *Request to re-docket the appeal.* The appellant may request that the Board re-docket the appeal (*see* §41.35(a) of this subpart) and file a reply brief as set forth in §41.41 of this subpart. A reply brief may not be accompanied by any amendment or evidence. A reply brief which is accompanied by an amendment or evidence will be treated as a request to reopen prosecution pursuant to paragraph (b)(1) of this section.

(c) *Remand not final action.* Whenever a decision of the Board includes a remand, the decision shall not be considered a final decision of the Board. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board may enter an order making its decision final.

(d) *New ground of rejection.* Should the Board have a basis not involved in the appeal for rejecting any pending claim, it may enter a new ground of rejection. A new ground of rejection shall be considered an interlocutory order and shall not be considered a final decision. If the Board enters a new ground of rejection, within two months appellant must exercise one of the following two options with respect to the new ground of rejection to avoid dismissal of the appeal as to any claim subject to the new ground of rejection:

(1) *Reopen prosecution.* Submit an amendment of the claims subject to a new ground of rejection or new evidence relating to the new ground of rejection or both, and request that the matter be reconsidered by the examiner. The application or reexamination proceeding on appeal will be remanded to the examiner. A new ground of rejection by the Board is binding on the examiner unless, in the opinion of the examiner, the amendment or new evidence overcomes the new ground of rejection. In the event the examiner maintains the new ground of rejection, appellant may again appeal to the Board.

(2) *Request for rehearing.* Submit a request for rehearing pursuant to §41.52 of this subpart relying on the Record.

(e) *Recommendation.* In its opinion in support of its decision, the Board may include a recommendation, explicitly designated as such, of how a claim on appeal may be amended to overcome a specific rejection. When the Board makes a recommendation, appellant may file an amendment or take other action consistent with the recommendation. An amendment or other action, otherwise complying with statutory patentability requirements, will overcome the specific rejection. An examiner, however, upon return of the application or reexamination proceeding to the jurisdiction of the examiner, may enter a new ground of rejection of a claim amended in conformity with a recommendation, when appropriate.

(f) *Request for briefing and information.* The Board may enter an order requiring appellant to brief matters or supply information or both that the Board believes would assist in deciding the appeal. Appellant will be given a non-extendable time period within which to respond to the order. Failure of appellant to timely respond to the order may result in dismissal of the appeal in whole or in part.

(g) *Extension of time to take action.* A request for an extension of time to respond to a request for briefing and information under paragraph (f) of this section is not authorized. A request for an extension of time to respond to Board action under paragraphs (b) and (d) of this section shall be presented as a petition under §41.3 of this part.

§ 41.52 Rehearing.

(a)(1) Appellant may file a single request for rehearing within two months of the date of the original decision of the Board. No request for rehearing from a decision on rehearing will be permitted, unless the rehearing decision so modified the original decision as to become, in effect, a new decision, and the Board states that a second request for rehearing would be permitted. The request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board. Arguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing except as permitted by paragraphs (a)(2) and (a)(3) of this section. When a request for rehearing is made,

the Board shall render a decision on the request for rehearing. The decision on the request for rehearing is deemed to incorporate the earlier opinion reflecting its decision for appeal, except for those portions specifically withdrawn on rehearing, and is final for the purpose of judicial review, except when noted otherwise in the decision on rehearing.

(2) Upon a showing of good cause, appellant may present a new argument based upon a recent relevant decision of either the Board or a Federal Court.

(3) New arguments responding to a new ground of rejection made pursuant to § 41.50(b) are permitted.

(b) Extensions of time under § 1.136(a) of this title for patent applications are not applicable to the time period set forth in this section. See § 1.136(b) of this title for extensions of time to reply for patent applications and § 1.550(c) of this title for extensions of time to reply for *ex parte* reexamination proceedings.

EFFECTIVE DATE NOTE: At 73 FR 32977, June 10, 2008, § 41.52 was revised, effective December 10, 2008. Per a subsequent final rule published at 73 FR 74972, Dec. 10, 2008, the effective date of this rule was delayed indefinitely.

For the convenience of the user, the revised text is set forth as follows:

§ 41.52 Rehearing.

(a) *Request for rehearing authorized.* An appellant may file a single request for rehearing.

(b) *Time for filing request for rehearing.* Any request for rehearing must be filed within two months from the date of the decision mailed by the Board.

(c) *Extension of time to file request for rehearing.* A request for an extension of time shall be presented as a petition under § 41.3 of this part.

(d) *Content of request for rehearing.* The form of a request for rehearing is governed by the requirements of § 41.37(v) of this subpart, except that a request for rehearing may not exceed 10 pages, excluding any table of contents, table of authorities, and signature block. A request to exceed the page limit shall be made by petition under § 41.3 at least ten calendar days before the request for rehearing is due. A request for rehearing must contain, under appropriate headings and in the order indicated, the following items:

(1) Table of contents—*see* § 41.37(i) of this subpart.

(2) Table of authorities—*see* § 41.37(j) of this subpart.

(3) [Reserved]

(4) Argument—*see* paragraph (f) of this section.

(e) [Reserved]

(f) *Argument.* A request for rehearing shall state with particularity the points believed to have been misapprehended or overlooked by the Board. In filing a request for rehearing, the argument shall adhere to the following format: "On page x, lines y-z of the Board's opinion, the Board states that (set out what was stated). The point misapprehended or overlooked was made to the Board in (identify paper, page and line where argument was made to the Board) or the point was first made in the opinion of the Board. The response is (state response)." As part of each response, appellant shall refer to the page number and line or drawing number of a document in the Record. A general restatement of the case will not be considered an argument that the Board has misapprehended or overlooked a point. A new argument cannot be made in a request for rehearing, except:

(1) *New ground of rejection.* Appellant may respond to a new ground of rejection entered pursuant to § 41.50(d)(2) of this subpart.

(2) *Recent legal development.* Appellant may rely on and call the Board's attention to a recent court or Board opinion which is relevant to an issue decided in the appeal.

(g) *No amendment or new evidence.* No amendment or new evidence may accompany a request for rehearing.

(h) *Decision on rehearing.* A decision will be rendered on a request for rehearing. The decision on rehearing is deemed to incorporate the underlying decision sought to be reheard except for those portions of the underlying decision specifically modified on rehearing. A decision on rehearing is final for purposes of judicial review, except when otherwise noted in the decision on rehearing.

§ 41.54 Action following decision.

After decision by the Board, the proceeding will be returned to the examiner, subject to appellant's right of appeal or other review, for such further action by appellant or by the examiner, as the condition of the proceeding may require, to carry into effect the decision.

EFFECTIVE DATE NOTE: At 73 FR 32977, June 10, 2008, § 41.54 was revised, effective December 10, 2008. Per a subsequent final rule published at 73 FR 74972, Dec. 10, 2008, the effective date of this action was delayed indefinitely.

For the convenience of the user, the revised text is set forth as follows:

CERTIFICATE OF SERVICE

United States Court of Appeals
for the Federal Circuit
No. 2011-1212,-1213

----------)
John Robert Adair, Appellants,

v.

Paul J. Carter, Cross Appellants.
----------)

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by COZEN O'CONNOR, Attorneys for Appellants to print this document. I am an employee of Counsel Press.

On the **13th of May 2011**, I served 2 copies of the **Brief of the Appellants John Robert Adair, Diljeet Singh Athwal and John Spencer Emtage** upon :

Oliver R. Ashe, Jr.
ASHE, P.C.
11440 Isaac Newton Square North
Suite 210
Reston, VA 20190
Tel: 703-467-9001
Fax: 703-467-9002

via Federal Express,

Unless otherwise noted, 12 copies have been delivered to the Court on the same date via Federal Express.

Elissa Matias

May 13, 2011

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2011-1212, -1213
(Interference No. 105,744)

JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL,
and JOHN SPENCER EMTAGE,
Appellants,

v.

PAUL J. CARTER and LEONARD G. PRESTA,
Cross Appellants.

Appeals from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences

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UNOPPOSED MOTION TO DISMISS CARTER'S CROSS-APPEAL

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June 9, 2011

CERTIFICATE OF INTEREST

Counsel for the Cross-Appellants certifies the following:

1. The full name of every party or amicus represented by me is:

PAUL J. CARTER and LEONARD G. PRESTA

2. The name of the real party in interest represented by me is:

GENENTECH, INC.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

ROCHE HOLDINGS, INC.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Oliver R. Ashe, Jr. of ASHE, P.C.
Jeffrey P. Kushan and Rachel H. Townsend of SIDLEY AUSTIN, LLP

Dated: June 9, 2011

Oliver R. Ashe, Jr.