Appendix 2 Statement of Material Facts Relied Upon in Motion.

Appendix 3 Claim chart comparing Adair claim 24 presented in 2005 and Adair involved claim 24.

Appendix 2

STATEMENT OF MATERIAL FACTS RELIED UPON IN MOTION

1. On December 21, 1989, Adair filed Great Britain Application GB 8928874.0 ("the UK Application"). (Ex. 2036).

2. On December 21, 1990, Adair filed PCT Application PCT/GB90/02017 ("the PCT Application"). (Ex. 2005).

3. Exhibit 2037 is a computer generated comparison (using Workshare™ Professional 5.2 SR2 software) of the typewritten text of the UK Application to the typewritten text of the PCT Application. The last page of Exhibit 2037 contains a color-coded legend for identifying deletions, additions, and movement of text.

4. On September 17, 1991, Adair entered the U.S. national stage by filing U.S. Patent Application No. 07/743,329 ("the '329 application"). (Ex. 2006).

5. Adair's '329 application contained claims 1-23, which are identical to claims 1-23 as originally filed with Adair's PCT application. (Ex. 2005, pp. 67-70 and Ex. 2006, pp. 67-70).

6. Original claim 1 of the Adair '329 application reads as follows:

> 1. 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. 2006, p. 67].

7. At pages 4-6 of the specification, Adair provides a discussion of "recent" disclosures by Queen *et al*. relating to CDR-grafted antibodies and the substitution of acceptor framework residues with donor residues. (Ex. 2002, pp. 4-6).

8. At page 6, lines 22-28, the Adair specification states:

> This has enabled us to establish a protocol for obtaining satisfactory CDR-grafted products which may be applied very widely irrespective of the level of homology between the donor immunoglobulin and acceptor framework. The set of residues which we have identified as being of critical importance does not coincide with the residues identified by Queen…." [Ex. 2002, p. 6, lns. 22-28].

9. The Abstract of Adair's involved specification reads, in part, as follows:

> CDR-grafted antibody heavy and light chains comprise acceptor framework and donor antigen binding regions, the heavy chains comprising 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, Abstract].

10. At page 6, lines 31-37, the Adair specification reads as follows:

> 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, p. 6, lns. 31-37].

11. At page 7, lines 1-5, the Adair specification reads as follows:

> 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, p. 7, lns. 1-5].

12. At page 16, line 30 to page 19, line 9, Adair describes its "preferred protocol" for obtaining CDR-grated antibodies. (Ex. 2002, p. 16, ln. 30 to p. 19, ln. 9).

13. At page 17, lines 27-30, the involved Adair specification reads as follows under a section titled "Protocol":

> 2. Heavy Chain
> 2.1 Choose donor residues at <u>all</u> of positions 23, 24, 49, 71, 73 and 78 of the heavy chain or <u>all</u> of positions 23, 24 and 49 (71, 73 and 78 are <u>always</u> either <u>all</u> donor or <u>all</u> acceptor). [Ex. 2002, p. 17, lns. 25-30; Emphasis added].

14. At page 17, lines 32-35, the involved Adair specification states:

> 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, p. 17, lns. 32-35].

15. At pages 19-23 of its involved specification, Adair offers a "rationale" for its protocol. (Ex. 2002, pp. 19-23).

16. At page 20, line 27, the involved Adair specification states "Heavy Chain - Key residues are 23, 71 and 73." (Ex. 2002, p. 20, ln. 27).

17. At page 21, line 9, for the "packing residues near the CDRs," the involved Adair specification states "Heavy Chain - Key residues are 24, 49 and 78." (Ex. 2002, p. 21, ln. 9).

18. At page 48, lines 25-27, the involved Adair specification explains: "the presence of the 6, 23 and 24 changes are important to maintain a binding affinity similar to that of the murine antibody." (Ex. 2002, p. 48, lns. 25-27).

19. At page 52, lines 25-29, the Adair involved specification states:

> These and other results lead us to the conclusion that of the 11 mouse framework residues used in the gH341A (JA185) construct, 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, lns. 25-29].

20. On November 18, 1992, the U.S. Patent and Trademark Office entered a non-final office action rejecting Adair's original claims 1-23 on various grounds. (Ex. 2038).

21. At page 5 of the November 1992 office action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, first paragraph as not being enabled. In particular, the Examiner stated that practicing the invention as claimed would require undue experimentation relative to the teachings of the Adair specification. (Ex. 2038, p. 5).

22. At page 6 of the November 1992 office action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, second paragraph, as being indefinite in their recitation of "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" because it was unclear whether the heavy chain,

a. had at least one of 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91, or alternatively,

b. had at least one of (6) or (23 and/or 24) or (48 and/or 49) or (71 and/or 73) or (75 and/or 76 and/or 78 and 88 and/or 91), or alternatively,

c. had at least one of (6, 23) and/or (24, 48) and/or (49, 71) and/or (73, 75) and 76 and/or (78 and 88) and/or (91). (Ex. 2038, p. 6).

23. At pages 7-12 of the November 1992 office action, the Examiner rejected Adair's claims under 102/103 in view of Riechmann *et al*., *Nature*, Vol. 332, pp. 323-327 (March 1988) and Queen *et al*., *Proc. Natl. Acad. Sci. USA*, Vol. 86, pp. 10029-10033 (December 1989) . (Ex. 2038, pp. 7-12; Ex. 2011, and Ex. 2023).

24. On January 19, 1993, Adair responded to the November 1992 Office action. (Ex. 2007).

25. In the January 1993 amendment, Adair responded to the rejection of claims under 35 U.S.C. § 112, second paragraph, by cancelling claims 1-12. (Ex. 2007, pp. 29-32).

26. In the January 19, 1993, amendment, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Riechmann *et al.* as follows:

> In Part A of this rejection, claims 1, 5, 6-8, and 12-22 were rejected as anticipated by Riechmann et al. The Examiner stated that claim 1 and claim 6 were interpreted to mean that the framework has donor residues in at least one of any of positions 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91 in the heavy chain and (1, 3, 46, or 47) or 46, 48, 58, or 71) in the light chain, and thus, the teachings of Riechmann et al. anticipate the invention as claimed.
>
> The Examiner contends that the original claims lacked novelty over Riechmann et al. Claims 1, 5, 6-8, 12 and 22 have been cancelled without prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.

> In present claims 24 and 25, it is specified that residues 23 and 24 in the heavy chain should be donor residues. However, as can be seen from Fig. 1, panel (a) in Riechmann et al., in the recombinant antibody shown there, residues 23 and 24 are acceptor residues. [Ex. 2007, p. 32-33].

27. In the January 19, 1993, response, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Queen *et al.* as follows:

> In Part B of the rejection, the Examiner rejected claims 1-6 and 12-22 as anticipated by Queen et al.
>
> Claims 1-6, 12-20 and 22 have been cancelled without prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.
>
> In present claims 24 and 25, it is specified that residues 48, 66, 67, 68, 93, 103 to 108 and 110 should all be acceptor residues. However, in Queen et al., as can be seen from Fig. 2B, in these positions Queen et al. uses donor, rather than acceptor, residues. It should again be borne in mind that Queen et al. does <u>not</u> use the Kabat numbering and it is therefore necessary to look carefully at the disclosure in Queen et al. before it is possible to come to any final conclusion. [Emphasis by Adair].
>
> In present claim 38, it is specified that residue 71 should be a donor residue. However, as can be seen from Fig. 2A of Queen et al., in that position Queen et al. uses an acceptor, rather than a donor residue.
>
> Applicants' claimed antigen-binding molecules are thus not anticipated by Queen et al. Withdrawal of this entire 35 USC § 102 (b) rejection is respectfully requested. [Ex. 2007, pp. 33-34].

28. At pages 26-28 of its January 19, 1993, response, Adair responded to the § 112, first paragraph rejection by arguing, *inter alia*, as follows:

> In contrast, the teaching in the present application can be applied without undue experimentation to any antibody. All that is required is experimentation following a protocol which is clearly set out in the description, in particular at page 16, line 30 to page 19, line 9. In order to follow this protocol, as a first step, it is necessary to determine the amino acid sequence of the donor chain. The sequence of the acceptor chain will already be known, for instance from a sequence data base.
>
> There is then no need to carry out computer modeling to determine which donor residues to substitute into the acceptor sequence. The protocol in the

present application provides the teaching directly. It instructs the skilled person to compare the two sequences and change certain specified residues in the acceptor sequence to donor residues.

Moreover, the present application provides a hierarchical structure of residues which can be considered. Thus, if changing the residues at the top of the structure does not provide adequate affinity, then a lower level of residues are considered, and so on until acceptable affinity is obtained.

[…]

It is submitted that this identifies where the present invention makes a significant departure from the prior art. The prior art indicates that each antibody has to be treated individually. In contrast, the present invention teaches that, by following the protocol set forth in the present application, it is possible to reshape any antibody. [Ex. 2007, pp. 26-28].

29. An Examiner Interview Summary Record dated January 27, 1993, states "applicant suggests that the 'comprising' in eg clm 24 is not to be taken as 'comprising' more residues than those in clm, i.e. claimed residues are not to be considered open ended. Applicant indicated they would clarify the latter issue. Queen does not teach changing residues: 73HC; 38HC; 71 on LC # 1 on LC + #4 on LC, 36 on LC 46 on LC." (Ex. 2039, p. 4; Emphasis by Examiner).

30. On April 7, 1993, Adair made the following statements in an amendment:

Having considered the Examiner's concerns that the language of the claims might be indefinite, because it was not clear whether the specified residues were the only or the minimum number of residues to be donor residues, the Applicants have amended the claims. In all the claims it is made clear that there is a minimum number of residues which have to be donor residues and a minimum number which have to be acceptor residues. Those residues which are not specified in the claims may be either donor or acceptor. [Ex. 2008, p. 13; Emphasis by Adair].

In claim 67, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that claim 67 is novel over the anti-TAC antibody disclosed by Queen. This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5, the Applicant considers that in general, residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2008, p. 14].

> It is stated on page 7, lines 1 to 5, that residues 71, 73 and 78 should all be either acceptor or donor. Claims 73, 80, 87, 94 and 101 cover the first alternative and claims 74, 81, 88, 95 and 102 cover the second alternative. [Ex. 2008, p. 15].

31. On September 9, 1993, in the Adair PCT/EP Patent Application 91901433.2, Adair filed an amendment deleting original claims 1-23 and replacing them with new claims 1-20 and made the following statements:

> 2.10. In new claim 1, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that new claim 1 is novel over the anti-TAC antibody disclosed in PNAS-USA, 86, 10029-10033, 1989 (Queen) (cited in the International Search Report). This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5, the Applicant considers that in general, residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2009, p. 3].

32. On February 7, 1994, Adair filed an amendment in the '329 application responding to the office action mailed on September 7, 1993 (Ex. 2028), wherein Adair stated:

> It is specifically stated in the application that the present protocol represents a departure from the procedures of Reichmann [sic] and Queen, at least. Thus, the skilled person would not rely on Reichmann [sic] and Queen as teachings relevant to whether the present description is enabling.
>
> It is submitted that the skilled person would rely on the clear teaching given in the application and find that it is enabling. The specification plainly sets out what actions need to be taken. It is presumed that the Examiner agrees that the skilled person could have taken those actions. The application also sets out that, contrary to the teachings of Reichmann and Queen, the protocol is generally applicable. The application further shows that it had been successfully implemented. Thus, it is submitted that the skilled person would find that the present application is properly enabled the full extent of the claims. [Ex. 2010, pp. 11-12].

33. In the February 7, 1994, amendment, Adair made the following statements:

> At a very helpful interview held at the beginning of 1993, there was some discussion of the word "comprising" as used in the claims under consideration at that time. In those claims, it was only specified that certain residues should be donor residues. [Emphasis by Adair]. It was considered that it was not clear whether these were the only residues which could be donor residues. The alternative view was that these were only the minimum number of residues which must be donor but that any of the other residues could also be donor.

If the second line of interpretation were taken, the claims could be read to cover a situation in which all except one of the residues in the variable domain were donor residues. [Emphasis by Adair]. In this case, the claims could then be interpreted to cover a structure similar to a "chimeric" antibody comprising a donor variable domain and a human constant region. Such chimeric antibodies were already well known at the priority date.

It plainly is not the intention of the Applicants to claim chimeric antibodies or any similar structures. As can be seen from the description, the superhumanised antibodies of the present invention are compared to the prior art chimeric antibodies. Moreover, the present invention was intended to deal with the problem of chimeric antibodies in that chimeric antibodies were believed to be too "foreign" because of the presence of the complete donor variable domain.

For the above reasons, it is clear that the wording of the claims needed to be changed so that the Applicants' intention of excluding chimeric antibodies was made effective. The language now present in the claims puts this intention clearly into effect.

As to support for this wording, the Examiner is referred firstly to page 16, under the heading "Protocol". It can be seen from this paragraph that the first step in the process involves the choice of an appropriate acceptor chain variable domain. This acceptor domain must be of known sequence. Thus, the protocol starts with a variable domain in which all the residues are acceptor residues. In the sentence bridging pages 16 and 17, it is stated that:

> "The CDR-grafted chain is then designed starting from the basis of the acceptor sequence". [Emphasis by Adair].

On page 17, in the middle paragraph, it is stated that:

> "The positions at which donor residues are to be substituted for acceptor in the framework are then chosen as follows ...."

This again shows that, unless a residue is chosen for substitution, it will remain as in the acceptor sequence.

It must also be borne in mind that the purpose of the invention is to obviate some of the disadvantages of prior art proposals. The proposal of using chimeric antibodies had the disadvantage that they were more "foreign" than desirable. The problem of making CDR-grafted antibodies was that they generally did not provide good recovery of affinity. Thus, the aim of the present invention was to minimise as far as possible the "foreign" nature of the antibody while maximising as far as possible its affinity.

Bearing the passages referred to above and the aim of the invention in mind, it would have been abundantly clear to the skilled person reading the application that as many residues as possible should remain as acceptor residues. If this were not the case, it could hardly be said that the composite chain is based on the acceptor sequence.

The skilled person reading the application can plainly see that certain residues have been considered for changing from acceptor to donor. These are clearly set out in the description. It would be plain to the skilled person that all other residues should not be considered for changing at all. It would therefore be obvious that any residue which is not specified as being under consideration for changing must remain as in the acceptor chain.

It may be that there is no explicit statement in the description that the specified residues should remain as in the acceptor chain. However, the disclosure in a specification is not limited to the explicit disclosure but also includes that which is implicit. It is implicit, in the recitation that the chain is based on the acceptor and that only certain residues are considered for changing, that all non-specified residues must remain as acceptor residues. Subject matter which might be fairly deduced from the disclosure is not new matter. *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074, 1080, 167 U.S.P.Q. 129, 132-133(6th Cir. 1970), *cert denied*, 401 U.S. 956 (1971).

Another way to look at it is to consider a different way in which the claim could be drafted. It could be specified that in the composite chain, at least a certain minimum number of residues are donor residues (as in the present claims) and at most a certain maximum number of residues are donor residues. The maximum number would be derived by listing all the residues which are considered for changing. Such an amendment would have clear explicit basis in the description because all those residues are mentioned as such. However, the effect of such an amendment would be to produce claims of exactly the same scope as the present claims. It can thus be seen that the present claims do not add subject matter but are plainly properly based on the disclosure in the description.

It is therefore submitted that the claims are fully supported by the description, are commensurate in scope with the disclosure in the description, and are properly delimited over the prior art. [Ex. 2010, pp. 3-7].

34. Adair did not present a newly executed declaration at the time of filing the ‘261 application but, rather, relied on the inventor declaration from the parent application to satisfy the requirements of 37 C.F.R. § 1.63. (Ex. 2002).

35. On November 21, 2005, Adair filed its involved application, *i.e.*, U.S. Patent Application No. 11/284,261 ("the '261 Application"). (Ex. 2002).

36. On November 21, 2005, Adair presented new claim 24 as follows:

> Claim 24 (new) 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. [Ex. 2003, p. 3].

37. On September 9, 2009, Adair presented its involved claim 24 in the '261 application, which reads as follows:

> Claim 24 (currently amended): 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. [Ex. 2004, p. 2; Adair Clean Copy of Claims, Paper No. 5, p. 4].

38. Appendix 3 is a claim chart comparing Adair claim 24 as originally filed in 2005 and Adair involved claim 24.

39. Adair involved claim 24 encompasses a humanized antibody wherein the heavy chain variable domain framework region has any combination of human and non-human amino acid residues at positions 23, 24, 49, 71, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

40. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at positions 71, 73 and 78 and human amino acids at positions 23, 24, and 49. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

41. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at positions 23 and 71 and human amino acids at positions 24, 49, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

42. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at position 23 and human amino acids at positions 24, 49, 71, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

Appendix 3

CLAIM CHART COMPARING
ADAIR CLAIM 24 PRESENTED IN 2005 AND ADAIR INVOLVED CLAIM 24

Adair Claim 24 Presented in 2005	Adair Involved Claim 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.	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.

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Paper 73
Filed: 16 June 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)

ORDER –Authorizing Oppositions – 125(a)

A conference call was held on 15 June 2010 at approximately 2:00 pm.

Participating in the call were:

(1) Oliver Ashe for Carter,

(2) Doreen Trujillo for Adair, and

(3) Sally Gardner Lane, Administrative Patent Judge.

Adair oppositions

Carter has filed two motions (Paper 71 and 72). The motions address threshold issues. Adair oppositions were not previously authorized. (Paper 23 at 3). After review of the motions, the Board has determined that it is appropriate to authorize Adair oppositions to the Carter motions. As requested by Adair, a four week time period is set for the filing of the Adair oppositions.[1,2]

As discussed during the call and as agreed to by the parties, Carter will be given a small amount of time in addition to that set out in Bd. R. 155(b)(1) to make any objections to evidence relied upon in the Adair oppositions.

No Carter reply to either of the Adair oppositions is authorized at this time.

Settlement conference

Adair noted that it has neglected to initiate the settlement conference required by the Standing Order at ¶ 126. 2. Adair indicated that it is awaiting a response from its real party in interest regarding plans for a settlement conference, however it is unlikely that settlement will occur.

Order

It is

ORDERED that Adair oppositions to Carter Motions 1 and 2 shall be filed on or before **14 July 2010**;

---

[1] Due to a health issue affecting Adair lead counsel, Adair has requested, and Carter has agreed to the request for, additional time than would ordinarily be authorized.

[2] Adair indicated that it does not wish to file a responsive motion and none is authorized. Adair should contact the Board and arrange a conference call immediately if Adair determines that it wishes to seek authorization to file a responsive motion.

FURTHER ORDERED that any Carter objections to evidence relied upon in the Adair opposition under Bd. R. 155(b) (1) shall be filed on or before **28 July 2010**; and

FURTHER ORDERED that Adair shall, within a reasonable time from the date of this Order, initiate the settlement negotiations required by the Standing Order (SO at ¶ 126.2).

/Sally Gardner Lane/
Administrative Patent Judge

cc (via electronic delivery):

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Paper No:_____
Date Filed: June 28, 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)

JOINT STATEMENT REGARDING SETTLEMENT EFFORTS

As required by ¶ 126.4 of the Standing Order ("S.O."; Paper No. 2), the parties hereby file this joint statement advising that settlement is not likely at this time. Both parties, however, are open to future discussions.

The parties believe that the conference call with Judge Lane required under S.O. ¶ 126.2 is not necessary because the parties are not engaged in settlement discussions. However, if Judge Lane would like a teleconference, counsel for Adair will arrange to schedule one.

The undersigned has been authorized to file this paper on behalf of both parties.

Respectfully submitted,

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Date: June 28, 2010

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Paper No:_____
Filed: July 14, 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)

ADAIR OPPOSITION 1

I. Adair Statement of the Precise Relief Requested

Adair requests that Carter Substantive Motion 1 ("CSM1") be denied. Adair's involved claim 24 is not barred by 35 U.S.C. §135(b)(1).

II. Evidence

The exhibit list is attached as Appendix 1.

III. Statement of Material Facts

The Statement of Material Facts is attached as Appendix 2.

IV. Argument

Adair will ultimately show that it is the first inventor of the invention of the Count. Specifically, claim 24 of the involved Adair application has a priority date that is almost **18 months** earlier than the earliest priority date claimed by Carter (Fact 54). Even if Adair is not entitled to its earliest priority date, its next priority date is the filing date of Adair's PCT application, which is almost **six months** before the earliest priority date claimed by Carter (Fact 51).

In CSM1, Carter alleges that Adair has not complied with 35 U.S.C. § 135(b)(1) and that, thus, Adair does not have standing to pursue this interference. As Adair shows below, Adair complied with 35 U.S.C. § 135(b)(1) and Adair does have standing to pursue this interference.

A. Adair Can Rely Upon Adair's PCT Application Claims

In footnote 5, on page 3 of CSM1, Carter alleges that Adair cannot rely on its original claims in Adair's PCT application because Adair cannot rely upon a PCT application to satisfy the requirements of 35 U.S.C. § 135(b)(1) as a matter of law. Carter, however, cites no law in support of this allegation; nor is Adair aware of any such law. Indeed, the Patent Statute

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Unless otherwise indicated, the same abbreviations as used in CSM1 are used herein.

provides that a PCT application designating the United States, which Adair's PCT application does (Fact 47), has the same effect from its filing date as a national application for patent regularly filed in the United States Patent & Trademark Office **except** as otherwise provided in Section **102(e)**; Section 135(b) is not so excepted (Fact 46). 35 U.S.C. § 363, emphasis added. Regardless, as Carter admits, the '329 application is a **national phase** of Adair's PCT application (Fact 5), which makes it entitled to the filing date of Adair's PCT application as it was filed within the requisite time frame to be so entitled (Facts 1 and 5). Accordingly, Adair can rely upon its original claims in Adair's PCT application, filed December 21, 1990 (Fact 50). Thus, Adair had claims to substantially the same subject matter as the Carter '213 patent over **12 years** before the critical date (Facts 37 and 50).

B. Adair Has Complied With 135(b)(1)

Carter advances three main arguments as to why Adair does not have standing to pursue this interference. As discussed below, each of Carter's arguments fails as lacking legal and/or factual support.

1. Adair's Is Not Required To Show That Its Pre-Critical Date Claims Are Patentable

On page 1, lines 15-16, of CSM1, Carter alleges that Adair must have presented a pre-critical date claim that is patentable to Adair. Beginning on page 4, line 21, through page 9, line 14, of CSM1, Carter continues along this vein, arguing that Adair is not "statutorily entitled" to any of its original PCT/U.S. claims. Carter relies, *inter alia*, on Adair's cancellation of its original PCT/U.S. claims as evidence that the claims were not patentable. On page 9, lines 11-14, of CSM1, Carter cites four cases allegedly to support its position that pre-critical date claims must be patentable. None of the cases cited by Carter, however, holds that the pre-critical date claims must be patentable. *See 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); *In re Curtis,* 354 F.3d 1347, 1353-54 (Fed. Cir. 2004). Indeed, as the Board has held previously, **canceled** claims can be relied upon to provoke an interference. *See Tezuka v. Wilson*, 224 USPQ 1030 (Bd. Pat. Int. 1984). Cartter's arguments requiring patentability of pre-critical date claims are unsupported.

2. Adair's Pre-Critical Date Claims Define Substantially The Same Subject Matter As The Carter '213 Patent Claims

On page 9, lines 17-21, of CSM1, Carter argues that none of Adair's pre-critical date claims can serve as a basis for compliance with § 135(b) because they do not define the same or substantially the same subject matter as an involved Carter '213 patent claim.[2] Carter asserts that each of Adair's pre-critical date claims differ in one or more material limitations relative to the Carter '213 patent claims. Carter, however, does not specify which material limitation(s) of the Carter '213 patent claims are lacking in Adair's pre-critical date claims. Rather, Carter circuitously argues that, because Adair's original PCT/U.S. claims were alleged to be indefinite, and Adair has not argued that Carter's involved claims are indefinite, Adair's original claims must differ from the Carter '213 patent claims in ways having "patentable significance (*i.e.*, in material limitations)." (CSM1, page 9, line 22, through page 10, line 2.)

Adair's response is that the burden is upon Carter, as the proponent of the motion, to identify which material limitations are lacking. Carter has not met its burden and, thus, this

[2] Carter repeatedly intimates throughout CSM1 that the claims need to be *identical* under 35 U.S.C. § 135(b). Section 135(b) does not, however, require that the claims be identical. Section 135(b) only requires that the **subject matter** of the claims be the **same or substantially the same** (Fact 45). Carter is wrong on both fronts.

motion should be dismissed outright. Nonetheless, Adair maintains that its pre-critical date claims are to substantially the same subject matter as the Carter '213 patent claims. Although Adair focused upon claims to the light chain in provoking this interference (*see* Fact 44), Adair also had heavy chain claims to substantially the same invention. Specifically, original claim 1 of Adair's PCT application recited the following:

> 1. 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.

(Fact 61, emphasis added.) Involved claim 66 of the Carter '213 patent recites the following:

> 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**, **73H, 76H, 78H**, and 93H, utilizing the numbering system set forth in Kabat.

(Fact 65, emphasis added.) Recitations which are the same in both original claim 1 of Adair's PCT application and claim 66 of the Carter '213 patent are highlighted in bold. Although original claim 1 of Adair's PCT application did not limit the donor residues to non-human as claim 66 of the Carter '213 patent does , dependent claim 16 did (Facts 44 and 62). Although original claim 1 of Adair's PCT application did not limit the framework to human, dependent claim 16 did (Facts 44 and 62). As is abundantly clear from the foregoing, original claim 16 of Adair's PCT application, as depending from claim 1, effectively contains **all** limitations of involved claim 66 of the Carter '213 patent.

Carter attempts to dismiss Adair's **original** pre-critical date claims on the basis of patentability, instead focusing upon certain of Adair's **non-original** pre-critical date claims

(CSM1, p. 10, l. 10, through p.12, l. 30). Carter then dismisses Adair's non-original pre-critical date claims by arguing that Adair's non-original pre-critical date claims recite positions that all must be donor residues, thereby distinguishing such claims from the Carter '213 patent claims. Carter never asserts, however, that Adair's non-original pre-critical date claims are patentable. Evidently, Carter holds Adair's original pre-critical date claims to a higher standard than the non-original pre-critical date claims. Regardless, as discussed above, Carter cites no support for its requirement for patentability of pre-critical date claims.

3. Materiality Of A Claim Limitation For Purposes Of Section 135(b) Is To Be Determined In View Of The Carter '213 Patent Claims

On page 13, lines 1-18, of CSM1, Carter argues that Adair's involved claim 24 is not entitled to the benefit of any pre-critical date claims because involved claim 24 lacks material limitations present in Adair's non-original pre-critical date claims. Again, Carter dismisses Adair's original pre-critical date claims as unpatentable. First, as noted above, Carter has not argued that Adair's non-original pre-critical date claims were patentable. Second, 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. 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. *See In re* Berger, 279 F.3d 975, 61 USPQ2d 1523 (Fed. Cir. 2002), citing *Corbett v. Chisolm*, 568 F.2d 759, 765-766, 196 USPQ 337, 342 (CCPA 1977).

The question to be asked, thus, is did the applicant add, or remove, a limitation to its claim after the critical date that was necessary to the patentability of the claims of the **Carter '213 patent**, not did the applicant add, or remove, a limitation necessary to the patentability of **its** own claim. Adair contends that when the materiality test is properly applied, it is clear that neither the original Adair claims present in Adair's PCT application, nor claim 24 involved in the

present interference, lacks any material limitations of the Carter '213 patent claims (Facts 44 and 61-62), nor has Carter argued the same. Indeed, if the test were to be applied as Carter asserts, it is difficult to see how one could ever provoke an interference, if one has made any claim amendments during prosecution of any application in its priority chain.

Further, if the test were to be applied as Carter asserts, a motion under § 135(b) effectively becomes a motion for failure to comply with written description under § 112, first paragraph. A review of Carter's first two substantive motions in this interference bears this out - the Statements of Material Facts are nearly identical. But, the question of whether or not there is written descriptive support for **a** claimed invention (under § 112, first paragraph) is very different from the question of whether or not **two** claimed inventions are to the same or substantially the same subject matter (under § 135(b)).

V. Conclusion

Adair requests that Carter Substantive Motion 1 be denied on the merits.

Respectfully submitted,

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APPENDIX 1

Carter Exhibits Relied Upon:

Ex. 2001 – U.S. Patent No. 6,407,213 to Carter *et al.,* issued June 18, 2002.

Ex. 2002 – U.S. Patent Application No. 11/284,261 to Adair *et al.,* filed November 21, 2005.

Ex. 2005 – PCT Application No. PCT/GB90/02017 to Adair *et al.,* filed December 21, 1990, published as WO 91/09967 on July 11, 1991.

Ex. 2006 -- U.S. Patent Application No. 07/743,329 to Adair *et al.,* filed September 17, 1991.

Ex. 2036 -- Great Britain Application No. 8928874.0 to Adair *et al.,* filed December 21, 1989.

APPENDIX 2

ADAIR RESPONSE TO CARTER STATEMENT OF MATERIAL FACTS

1. On December 21, 1989, Adair filed Great Britain Application No. 8928874.0 ("Adair UK Application"). (Ex. 2036).

ADMITTED

2. On December 21, 1990, Adair filed PCT/GB90/02017("Adair's PCT application"), which contained claims 1-23. (Ex. 2005, pp. 67-70).

ADMITTED

3. Exhibit 2037 is a computer generated comparison (using WorkshareTM Professional 5.2 SR2 software) of the typewritten text of the UK Application to the typewritten text of the PCT Application. The last page of Exhibit 2037 contains a color-coded legend for identifying deletions, additions, and movement of text.

UNABLE TO ADMIT OR DENY

4. The PCT Application contains a section titled "Protocol" that is not contained in the UK Application. (Ex. 2005, pp. 16-19; Ex. 2036; and Ex. 2037, pp. 10-11).

DENIED

5. On September 17, 1991, Adair entered the U.S. national stage by filing U.S. Patent Application No. 07/743,329 ("the `329 application"), claiming benefit to Adair's PCT application. (Ex. 2006).

ADMITTED

6. Adair's U.S. `329 application contained claims 1-23, which are identical to claims 1-23 as originally filed with Adair's PCT application. (Ex. 2005, pp. 67-70 and Ex. 2006, pp. 67-70).

ADMITTED

7. At page 6 of its involved specification, Adair stated:

> We have further investigated the preparation of CDR-grafted humanized antibody molecules and have identified a hierarchy of positions within the framework of the variable regions (i.e., outside both the Kabat CDRs and structural loops of the variable regions) at which the amino acid identities of the residues are important for obtaining CDR-grafted products with satisfactory binding affinity. This has enabled us to establish a protocol for obtaining satisfactory CDR-grafted products which may be applied very widely irrespective of the level of homology between donor immunoglobulin and acceptor framework. The set of residues which we have identified as being of critical importance does not coincide with the residues identified by Queen et al (9). [Ex. 2002, p. 6, lns. 15-28].

ADMITTED

8. At page 6, lines 31-37, the Adair specification reads as follows:

> 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, p. 6, lns. 31-37].

ADMITTED

9. At page 7, lines 1-5, the Adair specification reads as follows:

> 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, p. 7, lns. 1-5].

ADMITTED

10. At page 17, lines 27-30, the involved Adair specification reads as follows under a section titled "Protocol":

> 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). [Ex. 2002, p. 17, lns. 27-30].

ADMITTED

11. On November 18, 1992, the U.S. Patent and Trademark Office ("the USPTO") entered a non-final office action rejecting claims Adair's claims 1-23 on several statutory grounds. (Ex. 2038).

UNABLE TO ADMIT OR DENY. ADAIR DOESN'T KNOW WHEN THE OFFICE ACTION WAS ENTERED.

12. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1-12, 17 and 22-23 under 35 U.S.C. § 101 for lack of utility. (Ex. 2038, pp. 1-3).

DENIED

13. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1-16 and 22-23 under 35 U.S.C. § 112, first paragraph, for failing to adequately teach how to make and use the claimed invention. (Ex. 2038, pp. 3-6).

DENIED

14. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1-23 were rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Adair regarded as its invention. (Ex. 2038, pp. 6-7).

ADMITTED

15. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1, 5, 6-8, and 12-22 under 35 U.S.C. § 102(b) as being anticipated by Riechmann *et al., Nature,* Vol. 332, pp. 323-327 (March 1988). (Ex. 2038, pp. 7-9 and Ex. 2011).

ADMITTED

16. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1-6 and 12-22 under 35 U.S.C. § 102(b) as being anticipated by Queen *et al., Proc. Natl. Acad. Sci. 9 USA,* Vol. 86, pp. 10029-10033 (December 1989). (Ex. 2038, pp. 9-10 and Ex. 2023).

ADMITTED

17. On November 18, 1992, the USPTO rejected the original Adair `329 claims 1-21 under 35 U.S.C. § 103 as being obvious over Riechmann *et al.* and Queen *et al.*. (Ex. 2038, pp. 10-12).

ADMITTED

18. At pages 3-6 of the November 1992 office action, the Examiner rejected claims 1-16 and 22-23 for lack of enablement under § 112, first paragraph, on the grounds that **,** *inter alia,* the specification did not support making the range of residue changes recited in the claims and that the effects of the residue changes as described in Adair's original claims could not readily be predicted. (Ex. 2038, pp. 3-6).

DENIED

19. At page 6 of the November 1992 office action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, second paragraph, as being indefinite in their recitation of "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" because it was unclear to the Examiner whether the heavy chain,

a. had at least one of 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91, or alternatively,

b. had at least one of (6) or (23 and /or 24) or (48 and/or 49) or (71 and/or 73) or (75 and/or 76 and/or 78 and 88 and/or 91), or alternatively,

c. had at least one (6, 23) and/or (24, 48) and/or (49 , 71) and/or (73, 75) and 76 and/or (78 and 88) and/or (91). (Ex. 2038, p. 6).

DENIED

20. At page 9 of the November 1992 office action, the Examiner rejected Adair's claims in view of Riechmann *et al.,* noting that the Examiner interpreted the claims to mean that

the framework has donor residues at at least one of any of positions 6, 23, 24**,** 48, 49, 71, 73, 75, 76, 78, 88, or 91 in the heavy chain. (Ex. 2038, p. 9).

ADMITTED

21. In a January 19, 1993 amendment , Adair responded to the November 1992 Office action by cancelling original claims 1-20, 22 and 23, amending original claim 21, and adding new claims 24-66. (Ex. 2007, pp. 1-13).

DENIED

22. In the January 1993 amendment, Adair stated the following:

> In contrast, the teaching in the present application can be applied without any undue experimentation to any antibody. All that is required is experimentation following a protocol which is clearly set out in the description, in particular at page 16, line 30 to page 19, line 9... .
>
> There is then no need to carryout computer modeling to determine which donor residues to substitute in to the acceptor sequence. The protocol in the present application provides the teaching directly. It instructs the skilled person to compare the two sequences and change certain specified residues in the acceptor sequence to donor residues.
>
> ...Thus, producing recombinant chains and testing them for affinity merely involves routine experimentation following a protocol which is clearly defined in the application. [Ex. 2007, pp. 26-27; Emphasis added].

ADMITTED

23. In the January 1993 amendment, Adair stated the following:

> It is submitted that this identifies where the present invention makes a significant departure from the prior art. The prior art indicates that each antibody has to be treated individually. In contrast, the present invention teaches that, by following the protocol set forth in the present application, it is possible to reshape any antibody. [Ex. 2007, p. 28].

ADMITTED

24. In the January 1993 amendment, Adair responded to the rejection of claims under 35 U.S.C. § 112, second paragraph, by cancelling claims 1-12. (Ex. 2007, pp. 29-32).

DENIED

25. In the January 1993 amendment, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Riechmann *et al.* as follows:

> In Part A of this rejection, claims 1, 5, 6-8, and 12-22 were rejected as anticipated by Riechmann et al. The Examiner stated that claim 1 and claim 6 were interpreted to mean that the framework has donor residues in at least one of any of positions 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91 in the heavy chain and (1, 3, 46, or 47) or 46, 48, 58, or 71) in the light chain, and thus, the teachings of Riechmann et al. anticipate the invention as claimed.
>
> The Examiner contends that the original claims lacked novelty over Riechmann et al. Claims 1, 5, 6-8, 12 and 22 have been cancelled without prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.
>
> In present claims 24 and 25, it is specified that residues 23 and 24 in the heavy chain should be donor residues. However, as can be seen from Fig. 1, panel (a) in Riechmann et al., in the recombinant antibody shown there, residues 23 and 24 are acceptor residues. [Ex. 2007, p. 32-33].

DENIED

26. In the January 1993 amendment, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Queen *et al.* as follows:

> In Part B of the rejection, the Examiner rejected claims 1-6 and 12-22 as anticipated by Queen et al.
>
> Claims 1-6, 12-20 and 22 have been cancelled without prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.
>
> In present claims 24 and 25 , it is specified that residues 48, 66, 67, 68, 93, 103 to 108 and 110 should all be acceptor residues . However, in Queen et al., as can be seen from Fig . 2B, in these positions Queen et al. uses donor, rather than acceptor, residues . It should again be borne in mind that Queen et al. does <u>not</u> use the Kabat numbering and it is therefore necessary to look carefully at the disclosure in Queen et al. before it is possible to come to any final conclusion. [Emphasis by Adair].
>
> In present claim 38, it is specified that residue 71 should be a donor residue. However, as can be seen from Fig. 2A of Queen et al., in that position Queen et al. uses an acceptor, rather than a donor residue.

> Applicants' claimed antigen-binding molecules are thus not anticipated by Queen et al. Withdrawal of this entire 35 USC § 102 (b) rejection is respectfully requested. [Ex. 2007, pp. 33-34].

ADMITTED

27. An Examiner Interview Summary Record dated January 27, 1993, states "applicant suggests that the `comprising' in eg clm 24 is not to be taken as `comprising' more residues than those in clm, i.e. claimed residues are not to be considered open ended. Applicant indicated they would clarify the latter issue. Queen does not teach changing residues: 73HC; 38HC; 71 on LC # 1 on LC + #4 on LC, 36 on LC 46 on LC." (Ex. 2039, p. 4; Emphasis by Examiner).

ADMITTED

28. On September 9, 1993, in the Adair PCT/EP Patent Application 91901433.2, Adair filed an amendment deleting original claims 1-23 and replacing them with new claims 1-20 and made the following statements:

> 2.10. In new claim 1, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that new claim 1 is novel over the anti-TAC antibody disclosed in PNAS-USA, 86, 10029-10033 , 1989 (Queen) (cited in the International Search Report). This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5 , the Applicant considers that in general , residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2009, p. 3].

ADMITTED

29. On February 7, 1994, Adair filed an amendment in the `329 application responding to an office action mailed on September 7, 1993 (Ex. 2028), wherein Adair made the following statements:

> At a very helpful interview held at the beginning of 1993, there was some discussion of the word "comprising" as used in the claims under consideration at that time. In those claims, it was only specified that certain residues should be

donor residues. [Emphasis by Adair]. It was considered that it was not clear whether these were the only residues which could be donor residues. The alternative view was that these were only the minimum number of residues which must be donor but that any of the other residues could also be donor.

If the second line of interpretation were taken, the claims could be read to cover a situation in which all except one of the residues in the variable domain were donor residues. [Emphasis by Adair]. In this case, the claims could then be interpreted to cover a structure similar to a "chimeric" antibody comprising a donor variable domain and a human constant region. Such chimeric antibodies were already well known at the priority date.

It plainly is not the intention of the Applicants to claim chimeric antibodies or any similar structures. As can be seen from the description, the superhumanised antibodies of the present invention are compared to the prior art chimeric antibodies. Moreover, the present invention was intended to deal with the problem of chimeric antibodies in that chimeric antibodies were believed to be too "foreign" because of the presence of the complete donor variable domain.

For the above reasons, it is clear that the wording of the claims needed to be changed so that the Applicants' intention of excluding chimeric antibodies was made effective. The language now present in the claims puts this intention clearly into effect.

As to support for this wording, the Examiner is referred firstly to page 16, under the heading "Protocol". It can be seen from this paragraph that the first step in the process involves the choice of an appropriate acceptor chain variable domain. This acceptor domain must be of known sequence. Thus, the protocol starts with a variable domain in which all the residues are acceptor residues. In the. sentence bridging pages 16 and 17, it is stated that:

> "The CDR-grafted chain is then designed starting from the basis of the acceptor sequence". [Emphasis by Adair].

On page 17, in the middle paragraph, it is stated that:

> "The positions at which donor residues are to be substituted for acceptor in the framework are then chosen as follows ...."

This again shows that, unless a residue is chosen for substitution, it will remain as in the acceptor sequence.

It must also be borne in mind that the purpose of the invention is to obviate some of the disadvantages of prior art proposals. The proposal of using chimeric antibodies had the disadvantage that they were more "foreign" than desirable. The problem of making CDR-grafted antibodies was that they

generally did not provide good recovery of affinity. Thus, the aim of the present invention was to minimise as far as possible the "foreign" nature of the antibody while maximising as far as possible its affinity.

Bearing the passages referred to above and the aim of the invention in mind, it would have been abundantly clear to the skilled person reading the application that as many residues as possible should remain as acceptor residues. If this were not the case, it could hardly be said that the composite chain is based on the acceptor sequence.

The skilled person reading the application can plainly see that certain residues have been considered for changing from acceptor to donor. These are clearly set out in the description. It would be plain to the skilled person that all other residues should not be considered for changing at all. It would therefore be obvious that any residue which is not specified as being under consideration for changing must remain as in the acceptor chain.

It may be that there is no explicit statement in the description that the specified residues should remain as in the acceptor chain. However, the disclosure in a specification is not limited to the explicit disclosure but also includes that which is implicit. It is implicit, in the recitation that the chain is based on the acceptor and that only certain residues are considered for changing, that all non-specified residues must remain as acceptor residues. Subject matter which might be fairly deduced from the disclosure is not new matter. *Acme 21 Highway Products Corp. v. D.S. Brown Co.,* 431 F.2d 1074, 1080, 167 U.S.P.Q. 22 129, 132-133(6th Cir. 1970), *cert denied,* 401 U.S. 956 (1971).

Another way to look at it is to consider a different way in which the claim could be drafted. It could be specified that in the composite chain, at least a certain minimum number of residues are donor residues (as in the present claims) and at most a certain maximum number of residues are donor residues. The maximum number would be derived by listing all the residues which are considered for changing. Such an amendment would have clear explicit basis in the description because all those residues are mentioned as such. However, the effect of such an amendment would be to produce claims of exactly the same scope as the present claims. It can thus be seen that the present claims do not add subject matter but are plainly properly based on the disclosure in the description.

It is therefore submitted that the claims are fully supported by the description, are commensurate in scope with the disclosure in the description, and are properly delimited over the prior art. [Ex. 2010, pp. 3-7].

ADMITTED

30. Adair's non-original pre-critical date claims are grounded in the specific rules

governing the "hierarchy of residues" to which Adair attributed the patentability of its claims. (Ex. 2007-2010, 2012-2022, 2024-2027, 2029, 2031, and 2031-2035).

UNABLE TO ADMIT OR DENY

31. Appendix 3 is a claim chart comparing Adair claim 24 as originally filed in 2005 and Adair involved claim 24.

UNABLE TO ADMIT OR DENY

32. Appendix 4 is an accurate comparison of Adair original PCT claims 8 and 16 to Adair involved claim 24.

UNABLE TO ADMIT OR DENY

33. In an amendment filed on April 7, 1993, Adair amended a claim reciting residues 71, 73 and 78, stating the following:

> In claim 67, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that claim 67 is novel over the anti-TAC antibody disclosed by Queen. This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5, the Applicant considers that in general, residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2008, p. 14].

ADMITTED

34. In the April 1993 amendment, Adair stated the following:

> It is stated on page 7, lines 1 to 5, that residues 71, 73 and 78 should all be either acceptor or donor. Claims 73, 80, 87, 94 and 101 cover the first alternative and claims 74, 81, 88, 95 and 102 cover the second alternative. [Ex. 2008, p. 15].

ADMITTED

35. In an Amendment filed on February 7, 1994, in the `329 application, Adair stated the following:

> It is specifically stated in the application that the present protocol represents a departure from the procedures of Reichmann [sic] and Queen, at least. Thus, the skilled person would not rely on Reichmann [sic] and Queen as

teachings relevant to whether the present description is enabling.

> It is submitted that the skilled person would rely on the clear teaching given in the application and find that it is enabling. The specification plainly sets out what actions need to be taken. It is presumed that the Examiner agrees that the skilled person could have taken those actions. The application also sets out that, contrary to the teachings of Reichmann and Queen, the protocol is generally applicable. The application further shows that it had been successfully implemented. Thus, it is submitted that the skilled person would find that the present application is properly enabled the full extent of the claims. [Ex. 2010, pp. 11-12].

DENIED

36. Carter's involved U. S. Patent No. 6,407,213 ("the `213 patent") issued on June 18, 2002. (Ex. 2001).

ADMITTED

37. One year from the date on which the Carter `213 patent issued is June 18, 2003. (Ex. 2001).

ADMITTED

38. On November 21, 2005, Adair filed its involved application 11/284,261 ("the 261 application"). (Ex. 2002).

ADMITTED

39. On November 21, 2005, Adair presented new claim 24 as follows:

> Claim 24 (new) 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. [Ex. 2003, p. 3].

ADMITTED

40. On September 9, 2009, Adair presented its involved claim 24 in the `261

application, which reads as follows:

> Claim 24 (currently amended): 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. [Ex. 2004, p. 2; Adair Clean Copy of Claims, Paper No. 5, p. 4].

ADMITTED

41. None of Adair's pre-critical date claims is identical to a Carter `213 patent claim.

(Ex.2001, 2005-2010, 2012-2022, 2024-2027, 2029, 2031, and 2031-2035).

UNABLE TO ADMIT OR DENY

42. None of Adair's pre-critical date claims is identical to Adair's involved claim 24.

(Ex. 2005-2010, 2012-2022, 2024-2027, 2029, 2031, and 2031-2035 and Adair Clean Copy Of Claims, Paper No. 5, p. 4).

UNABLE TO ADMIT OR DENY

43. Concurrent with the filing of the `261 application, Adair filed a "Preliminary Amendment and Request for Interference under 37 CFR § 42.202 [sic]." (Ex. 2003).

ADMITTED

44. On page 4 of the 2005 amendment, Adair stated the following:

> **(b) Compliance with 35 USC § 135(b)**
> Although the present rules do not require a showing of compliance under 35 USC § 135(b), Applicants submit the following to advance the examination of the present application to allowability. [...] Claims 1-23 as filed in the PCT application are attached as Appendix A.
>
> Under 35 USC § 135(b)(1), Applicants must show that they had a claim to the same, or substantially the same, subject matter as a claim of the 213 patent within one year of the issuance of the 213 patent, or June 18, 2003. The 213 patent issued on June 18, 2002. The PCT application was filed on December 21, 1990, over 10 years earlier than the 213 patent issued. The time limit of Section 135(b)(1) has been complied with fully. See *Corbett v. Chisholm,* 196 USPQ 337

(CCPA 1977).

To meet the "same or substantially the same invention" requirement of Section 135(b)(1), Applicants must show that their claim contained all material limitations, i.e. limitations necessary to patentability, of the claim of the 213 patent alleged to be to the same, or substantially the same, invention. *Corbett v. Chisholm,* 196 USPQ 337 (C.C.P.A. 1977), *citing Wetmore v. Miller,* 477 F.2d 960,177 USPQ 699 (C.C.P.A. 19730).

As is evident from Appendix A, Applicants made a claim for the same, or substantially the same, subject matter as a claim of the 213 patent well before the issuance of the 213 patent. Claim 16 of the PCT application, as depending from claim 8, is to substantially the same subject matter as at least claim 1 of the 213 patent. For the Office's convenience, all three claims are duplicated below.

> **Claim 8 of the PCT application**: 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.
>
> **Claim 16 of the PCT application**: 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.
>
> **Claim 1 of the 213 patent**: 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. [Ex. 2003, pp. 4-6; Emphasis by Adair.]

ADMITTED

ADAIR STATEMENT OF ADDITIONAL MATERIAL FACTS

45. Section 135(b) of the Patent Statute does not require Adair to have a pre-critical date claim identical to a claim of the Carter '213 patent. (*See* 35 U.S.C. § 135(b) and CSM1, p. 1, lines 17-18.)

46. Section 363 of the Patent Statute gives an international application designating the United States, e.g., a Patent Cooperation Treaty ("PCT") application designating the United States, the same effect from its filing date as a national application for patent regularly filed in the United States Patent & Trademark Office except as otherwise provided in Section 102(e). (35 U.S.C. § 363.)

47. Adair's PCT application designates the United States. (Ex. 2005, first page.)

48. The application that issued as the Carter '213 patent was filed as national phase of a PCT application that was filed on June 15, 1992 ("the Carter PCT application"). (Ex. 2001, first page.)

49. The Carter PCT application was filed as a continuation-in-part of Application Serial No. 07/715,272, filed on June 14, 1991 ("the Carter '272 application"). (Ex. 2001, first page.)

50. Adair's PCT application was filed on December 21, 1990. (Fact 2.)

51. Adair's PCT application was filed almost six months before the Carter '272 application. (Facts 49 and 50.)

52. Adair's PCT application was filed almost 18 months before the Carter PCT application. (Facts 48 and 50.)

53. The Adair UK application was filed on December 21, 1989. (Fact 1.)

54. The Adair UK application was filed almost 18 months before the Carter '272 application was filed. (Facts 53 and 49.)

55. The Adair UK application was filed almost 30 months before the Carter PCT application was filed. (Facts 53 and 48.)

56. Adair's PCT application published on July 11, 1991. (Ex. 2005, first page.)

57. The Carter '272 application was filed less than one month before the Adair PCT application published. (Facts 49 and 56.)

58. On page 16, lines 23-28, the Adair specification reads as follows:

> 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 rationa1e are given **without prejudice to the generality of the invention as hereinbefore described and defined**.

(Ex. 2002, p. 16, ll. 23-28, emphasis added.)

59. At page 6, lines 31-37, under the heading "Summary of the Invention," the Adair specification reads as follows:

> 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, p. 6, ll. 31-37).

60. On page 17, lines 1-5, the Adair specification states that

> [i]t will be appreciated that in some cases the donor and acceptor amino acid residues may be identical at a particular position thus no change of acceptor framework residue is required.

(Ex. 2002, p. 17, ll. 1-5.)

61. Claim 1 of Adair's PCT application recites the following:

> 1. 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, page 67.)

62. Claim 16 of Adair's PCT application recites the following:

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.

(Ex. 2005, page 69.)

63. Claim 1 of Adair's PCT application does not require that any residues be changed to donor. (Ex. 2005, claim 1, p. 67.)

64. Original claim 1 of the '329 application does not require that any residues be changed to donor. (Ex. 2006, claim 1, p. 67.)

65. Claim 66 of the Carter '213 patent recites the following:

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**, **73H, 76H, 78H**, and 93H, utilizing the numbering system set forth in Kabat.

(Carter Clean Copy of Claims, Paper No. 12, filed February 19, 2010.)

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Paper No:_____
Filed: July 14, 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)

ADAIR OPPOSITION 2

I. Adair Statement of the Precise Relief Requested

Adair requests that Carter Substantive Motion 2 ("CSM2") be denied. Adair's involved claim 24 is not barred under 35 U.S.C. § 112, first paragraph, for lack of written description.

II. Evidence

The exhibit list is attached as Appendix 1.

III. Statement of Material Facts

The Statement of Material Facts is attached as Appendix 2.

IV. Argument

Adair will ultimately show that it is the first inventor of the invention of the Count. Specifically, claim 24 of the '261 application has a priority date that is almost **18 months** earlier than the earliest priority date claimed by Carter (Fact 49). Even if Adair is not entitled to its earliest priority date, its next priority date is the filing date of Adair's PCT application, which is almost **six months** before the earliest priority date claimed by Carter (Fact 47).

In CSM2, Carter alleges that Adair has not complied with 35 U.S.C. § 112, first paragraph, for lack of written description and that, thus, Adair does not have standing to pursue this interference. As Adair shows below, however, Adair has complied with 35 U.S.C. § 112, first paragraph, for written description and Adair does have standing to be in this interference.

The bulk of CSM2 relies upon what is set forth as a specific protocol to support Carter's argument that there is no written descriptive support for involved claim 24 in the '261 application specification (CSM2, p. 8, l. 6, though p. 13, l. 5). Although Carter acknowledges that Adair used the terminology "preferred" in reference to the protocol, it argues that the remainder of the specification and the prosecution history show that Adair believed that

---

Unless otherwise indicated, the same abbreviations as used in CSM1 are used herein.

following the preferred protocol was necessary to distinguish its invention from the prior publications of others and to establish support for its claims (CSM2, p. 9, l. 21, through p. 10, l. 2). As discussed below, neither the remainder of the specification nor the prosecution history supports Carter's assertions.

First, the specification of the '261 application makes it clear that the invention is **not** to be limited to a preferred protocol. The specification of the '261 application contains the following text:

> 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 rationa1e are given **without prejudice to the generality of the invention as hereinbefore described and defined**.

(Fact 53.) Notably, the foregoing text is not cited anywhere in CSM2. And, as admitted by Carter, on page 6, lines 31-37, under the heading "Summary of the Invention," the specification of the '261 application reads as follows:

> 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.

(Fact 54, emphasis added.) The foregoing recitation clearly encompasses a framework region comprising an amino acid substitution **at any one** of residues 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, and 91.

As further evidence that the invention is not limited to the preferred protocol, on page 48, lines 24-27, of the '261 application, it is reported that changes at residues 6, 23, and 24, were important for maintaining a binding affinity similar to that of the murine antibody (Fact 55). Residue 49 is notably absent from the foregoing listing. On page 58, lines 1-6, of the '261

application, it is reported that the change of a **single** residue in the heavy chain, residue 73, was sufficient to generate an antibody with binding properties similar to the donor (Fact 56). Finally, the specification of the '261 application ends with the following statement:

> It will be appreciated that the foregoing examples are given by way of illustration only and are not intended to limit the scope of the claimed invention. Changes and modifications may be made to the methods described whilst still falling within the spirit and scope of the invention.

(Fact 57.) Such a recitation has been recognized by the Court of Appeals for the Federal Circuit ("Federal Circuit") to preclude limiting inventions to specific embodiments. *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 457 F3d 1284, 1290, 79 USPQ2d 1583, 1588 (Fed. Cir. 2006). Indeed, the Federal Circuit has repeatedly cautioned against unduly limiting the claims based upon embodiments in the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323, 75 USPQ2d 1321, 1334 (Fed. Cir. 2005). Contrary to Carter's assertions, the "entirety" of the Adair specification did not clearly indicate the invention is of a much narrower scope.

Second, the prosecution history makes it clear that the invention is **not** to be limited to the preferred protocol. On page 11, lines 26-27, of CSM2, Carter acknowledges that Adair's arguments in the prosecution history use equivocal terms like "in general", "can be", and "should be" when drawing substance from what Carter alleges to be the "rules" set forth in the specification (CSM2, p. 11, ll. 26 -27). Carter tries to trivialize the impact of such equivocal arguments by alleging that they are not consistent with the express teachings of the specification and, thus, that they should not be substituted for written description in the originally filed application (CSM2, p. 12, ll. 1-2). As noted above, however, such arguments are consistent with the express teachings of the specification. Regardless, contrary to Carter's assertion, the foregoing clearly shows that the prosecution history contains arguments that do **not** support

Carter's position. As such, the prosecution history does not unequivocally support limiting the invention to the preferred protocol.

On page 12, ll. 27-30, of CSM2, Carter argues that Adair relied upon the preferred protocol as providing the basis for distinguishing claims specifying substitutions at positions corresponding to those recited in Adair's involved claim 24 over the prior art, i.e., Riechmann et al. (Ex. 2011) and Queen et al. (Ex. 2023). What Carter fails to appreciate, however, is that the Adair claims at the time of the rejections were not limited to making substitutions to donor, but also included the instance in which the donor and acceptor residues were the same at the recited positions, and were so interpreted by the examiner (Facts 59-64). It is clear from Carter's own arguments that the recitation of the *substitution* of a single residue in the claims would have been sufficient to overcome the cited art – e.g., residue 24 or 73 (CSM2, p. 10, ll. 11-15 and p. 4, ll. 4-10 citing Facts 26-27 and 30). If that were not the case, Carter's involved claims 66-68, 70-71, 78, and 80-82 would be invalid over the same art (Fact 65). Carter's arguments regarding such amendments are not relevant to Adair's involved claim 24, which requires a substitution at residue 23, 24, 49, 71, 73, or 78, or combinations thereof (Fact 37).

V. Conclusion

Adair requests that Carter Substantive Motion 2 be denied on the merits.

Respectfully submitted,

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APPENDIX 1

Carter Exhibits Relied Upon:

Ex. 2001 – U.S. Patent No. 6,407,213 to Carter *et al.,* issued June 18, 2002.

Ex. 2002 – U.S. Patent Application No. 11/284,261 to Adair *et al.,* filed November 21, 2005.

Ex. 2005 – PCT Application No. PCT/GB90/02017 to Adair *et al.,* filed December 21, 1990, published as WO 91/09967 on July 11, 1991.

Ex. 2006 -- U.S. Patent Application No. 07/743,329 to Adair *et al.,* filed September 17, 1991.

Ex. 2011 – Riechmann *et al., Nature,* Vol. 332, pp. 323-327 (March 1988).

Ex. 2023 – Queen *et al., Proc. Natl. Acad. Sci. USA,* Vol. 86, pp. 10029-10033 (December 1989).

Ex. 2036 -- Great Britain Application No. 8928874.0 to Adair *et al.,* filed December 21, 1989.

Ex. 2038 -- Office Action mailed November 18, 1992, in U.S. Patent Application No. 07/743,329 to Adair *et al.*

APPENDIX 2

ADAIR RESPONSE TO CARTER STATEMENT OF MATERIAL FACTS

1. On December 21, 1989, Adair filed Great Britain Application GB 8928874.0 ("the UK Application"). (Ex. 2036).

ADMITTED

2. On December 21, 1990, Adair filed PCT Application PCT/GB90/02017 ("the PCT Application"). (Ex. 2005).

ADMITTED

3. Exhibit 2037 is a computer generated comparison (using WorkshareTM Professional 5.2 SR2 software) of the typewritten text of the UK Application to the typewritten text of the PCT Application. The last page of Exhibit 2037 contains a color-coded legend for identifying deletions, additions, and movement of text.

UNABLE TO ADMIT OR DENY

4. On September 17, 1991, Adair entered the U.S. national stage by filing U.S. Patent Application No. 07/743,329 ("the `329 application"). (Ex. 2006).

ADMITTED

5. Adair's `329 application contained claims 1-23, which are identical to claims 1-23 as originally filed with Adair's PCT application. (Ex. 2005, pp. 67-70 and Ex. 2006, pp. 67-70).

ADMITTED

6. Original claim 1 of the Adair `329 application reads as follows:

> 1. 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. 2006, p. 67].

ADMITTED

7. At pages 4-6 of the specification, Adair provides a discussion of "recent" disclosures by Queen *et al.* relating to CDR-grafted antibodies and the substitution of acceptor framework residues with donor residues. (Ex. 2002, pp. 4-6).

DENIED

8. At page 6, lines 22-28, the Adair specification states:

> This has enabled us to establish a protocol for obtaining satisfactory CDR-grafted products which may be applied very widely irrespective of the level of homology between the donor immunoglobulin and acceptor framework. The set of residues which we have identified as being of critical importance does not coincide with the residues identified by Queen...." [Ex. 2002, p. 6, lns. 22-28].

DENIED

9. The Abstract of Adair's involved specification reads, in part, as follows:

> CDR-grafted antibody heavy and light chains comprise acceptor framework and donor antigen binding regions, the heavy chains comprising 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, Abstract].

ADMITTED THAT THIS IS WHAT IS STATED IN THE SECTION DESIGNATED AS "ABSTRACT" ON BOARD ASSIGNED PAGE # 544 OF EX. 2002.

10. At page 6, lines 31-37, the Adair specification reads as follows:

> 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, p. 6, lns. 31-37].

ADMITTED

11. At page 7, lines 1-5 , the Adair specification reads as follows:

> 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, p. 7, lns. 1-5].

ADMITTED

12. At page 16, line 30 to page 19, line 9, Adair describes its "preferred protocol" for obtaining CDR-grated antibodies. (Ex. 2002, p. 16, ln. 30 to p. 19, ln. 9).

ADMITTED

13. At page 17 , lines 27-30, the involved Adair specification reads as follows under a section titled "Protocol":

> 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). [Ex. 2002, p. 17, lns. 25-30; Emphasis added].

ADMITTED

14. At page 17, lines 32-35, the involved Adair specification states:

> 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, p. 17, lns. 32-35].

ADMITTED

15. At pages 19-23 of its involved specification, Adair offers a "rationale" for its protocol. (Ex. 2002, pp. 19-23).

ADMITTED

16. At page 20, line 27, the involved Adair specification states "Heavy Chain - Key residues are 23, 71 and 73." (Ex. 2002, p. 20, ln. 27).

ADMITTED

17. At page 21, line 9, for the "packing residues near the CDRs," the involved Adair specification states "Heavy Chain - Key residues are 24, 49 and 78." (Ex. 2002, p. 21, ln. 9).

ADMITTED

18. At page 48, lines 25-27, the involved Adair specification explains: "the presence of the 6, 23 and 24 changes are important to maintain a binding affinity similar to that of the murine antibody ." (Ex. 2002, p. 48, lns . 25-27).

ADMITTED

19. At page 52, lines 25-29, the Adair involved specification states:

> These and other results lead us to the conclusion that of the 11 mouse framework residues used in the gH341A (JA185) construct, 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, lns. 25-29].

ADMITTED

20. On November 18, 1992, the U.S. Patent and Trademark Office entered a non-final office action rejecting Adair's original claims 1-23 on various grounds. (Ex. 2038).

UNABLE TO ADMIT OR DENY. ADAIR DOES NOT KNOW WHEN THE OFFICE ACTION WAS ENTERED.

21. At page 5 of the November 1992 office action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, first paragraph as not being enabled. In particular, the Examiner stated that practicing the invention as claimed would require undue experimentation relative to the teachings of the Adair specification. (Ex. 2038, p. 5).

DENIED

22. At page 6 of the November 1992 office action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, second paragraph, as being indefinite in their recitation of "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" because it was unclear whether the heavy chain,

a. had at least one of 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91, or

alternatively,

b. had at least one of (6) or (23 and/or 24) or (48 and/or 49) or (71 and/or 73)

or (75 and/or 76 and/or 78 and 88 and/or 91), or alternatively,

c. had at least one of (6, 23) and/or (24, 48) and/or (49, 71) and/or (73, 75)

and 76 and/or (78 and 88) and/or (91). (Ex. 2038, p. 6).

ADMITTED

23. At pages 7-12 of the November 1992 office action, the Examiner rejected Adair's claims under 102/103 in view of Riechmann *et al., Nature,* Vol. 332, pp. 323-327 (March 1988) and Queen *et al., Proc. Natl. Acad. Sci. USA,* Vol. 86, pp. 10029-10033 (December 1989). (Ex. 2038, pp. 7-12; Ex. 2011, and Ex. 2023).

DENIED

24. On January 19, 1993, Adair responded to the November 1992 Office action. (Ex. 2007).

ADMITTED

25. In the January 1993 amendment, Adair responded to the rejection of claims under 35 U.S.C. § 112, second paragraph, by cancelling claims 1-12. (Ex. 2007, pp. 29-32).

DENIED

26. In the January 19, 1993, amendment, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Riechmann *et al.* as follows:

> In Part A of this rejection, claims 1, 5, 6-8, and 12-22 were rejected as anticipated by Riechmann et al. The Examiner stated that claim 1 and claim 6 were interpreted to mean that the framework has donor residues in at least one of any of positions 6, 23, 24, 48, 49, 71, 73, 75, 76, 78, 88, or 91 in the heavy chain and (1, 3, 46, or 47) or 46, 48, 58, or 71) in the light chain, and thus, the teachings of Riechmann et al. anticipate the invention as claimed.
>
> The Examiner contends that the original claims lacked novelty over Riechmann et al. Claims 1, 5, 6-8, 12 and 22 have been cancelled without

prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.

In present claims 24 and 25, it is specified that residues 23 and 24 in the heavy chain should be donor residues. However, as can be seen from Fig. 1, panel (a) in Riechmann et al., in the recombinant antibody shown there, residues 23 and 24 are acceptor residues. [Ex. 2007, p. 32-33].

DENIED

27. In the January 19, 1993, response, Adair responded to the rejection of claims under 35 U.S.C. § 102(b) in view of Queen *et al.* as follows:

In Part B of the rejection, the Examiner rejected claims 1-6 and 12-22 as anticipated by Queen et al.

Claims 1-6, 12-20 and 22 have been cancelled without prejudice and submitted as new claims that more distinctly point out certain aspects of the present invention.

In present claims 24 and 25, it is specified that residues 48, 66, 67, 68, 93, 103 to 108 and 110 should all be acceptor residues. However, in Queen et al., as can be seen from Fig. 213, in these positions Queen et al. uses donor, rather than acceptor, residues. It should again be borne in mind that Queen et al. does not use the Kabat numbering and it is therefore necessary to look carefully at the disclosure in Queen et al. before it is possible to come to any final conclusion. [Emphasis by Adair].

In present claim 38, it is specified that residue 71 should be a donor residue. However, as can be seen from Fig. 2A of Queen et al., in that position Queen et al. uses an acceptor, rather than a donor residue.

Applicants' claimed antigen-binding molecules are thus not anticipated by Queen et al. Withdrawal of this entire 35 USC § 102 (b) rejection is respectfully requested. [Ex. 2007, pp. 33-34].

ADMITTED

28. At pages 26-28 of its January 19, 1993 , response , Adair responded to the § 112, first paragraph rejection by arguing, *inter alia,* as follows:

In contrast, the teaching in the present application can be applied without undue experimentation to any antibody. All that is required is experimentation following a protocol which is clearly set out in the description, in particular at

page 16, line 30 to page 19, line 9. In order to follow this protocol, as a first step, it is necessary to determine the amino acid sequence of the donor chain. The sequence of the acceptor chain will already be known, for instance from a sequence data base.

There is then no need to carry out computer modeling to determine which donor residues to substitute into the acceptor sequence. The protocol in the present application provides the teaching directly. It instructs the skilled person to compare the two sequences and change certain specified residues in the acceptor sequence to donor residues.

Moreover, the present application provides a hierarchical structure of residues which can be considered. Thus, if changing the residues at the top of the structure does not provide adequate affinity, then a lower level of residues are considered, and so on until acceptable affinity is obtained.

[. . .]

It is submitted that this identifies where the present invention makes a significant departure from the prior art. The prior art indicates that each antibody has to be treated individually. In contrast, the present invention teaches that, by following the protocol set forth in the present application, it is possible to reshape any antibody. [Ex. 2007, pp. 26-28].

ADMITTED

29. An Examiner Interview Summary Record dated January 27, 1993, states "applicant suggests that the `comprising' in eg clm 24 is not to be taken as `comprising' more residues than those in c1m, i.e. claimed residues are not to be considered open ended. Applicant indicated they would clarify the latter issue. Queen does not teach changing residues: 73HC; 38HC; 71 on LC # 1 on LC + #4 on LC, 36 on LC 46 on LC." (Ex. 2039, p. 4; Emphasis by Examiner).

ADMITTED

30. On April 7, 1993, Adair made the following statements in an amendment:

Having considered the Examiner's concerns that the language of the claims might be indefinite, because it was not clear whether the specified residues were the only or the minimum number of residues to be donor residues, the Applicants have amended the claims. In all the claims it is made clear that there

is a minimum number of residues which have to be donor residues and a minimum number which have to be acceptor residues. Those residues which are not specified in the claims may be either donor or acceptor. [Ex. 2008, p. 13; Emphasis by Adair].

In claim 67, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that claim 67 is novel over the anti-TAC antibody disclosed by Queen. This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5, the Applicant considers that in general, residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2008, p. 14].

It is stated on page 7, lines 1 to 5, that residues 71, 73 and 78 should all be either acceptor or donor. Claims 73, 80, 87, 94 and 101 cover the first alternative and claims 74, 81, 88, 95 and 102 cover the second alternative. [Ex. 2008, p. 15].

UNABLE TO ADMIT OR DENY

31. On September 9, 1993, in the Adair PCT/EP Patent Application 91901433.2, Adair filed an amendment deleting original claims 1-23 and replacing them with new claims 1-20 and made the following statements:

2.10. In new claim 1, it has been specified that residues 71, 73 and 78 are all donor residues in order to ensure that new claim 1 is novel over the anti-TAC antibody disclosed in PNAS-USA, 86, 10029-10033, 1989 (Queen) (cited in the International Search Report). This anti-TAC antibody has an acceptor residue at residue 73. However, as can be seen from page 7, lines 1 to 5, the Applicant considers that in general, residues 71, 73 and 78 can be either all donor or all acceptor. [Ex. 2009, p. 3].

ADMITTED

32. On February 7, 1994, Adair filed an amendment in the `329 application responding to the office action mailed on September 7, 1993 (Ex. 2028), wherein Adair stated:

It is specifically stated in the application that the present protocol represents a departure from the procedures of Reichmann [sic] and Queen, at least. Thus, the skilled person would not rely on Reichmann [sic] and Queen as teachings relevant to whether the present description is enabling.

It is submitted that the skilled person would rely on the clear teaching given in the application and find that it is enabling. The specification plainly sets out what actions need to be taken. It is presumed that the Examiner agrees that

the skilled person could have taken those actions. The application also sets out that, contrary to the teachings of Reichmann and Queen, the protocol is generally applicable. The application further shows that it had been successfully implemented. Thus, it is submitted that the skilled person would find that the present application is properly enabled the full extent of the claims. [Ex. 2010, pp. 11-12].

DENIED

33. In the February 7, 1994, amendment, Adair made the following statements:

At a very helpful interview held at the beginning of 1993, there was some discussion of the word "comprising" as used in the claims under consideration at that time. In those claims, it was only specified that certain residues should be donor residues. [Emphasis by Adair]. It was considered that it was not clear whether these were the only residues which could be donor residues. The alternative view was that these were only the minimum number of residues which must be donor but that any of the other residues could also be donor.

If the second line of interpretation were taken, the claims could be read to cover a situation in which all except one of the residues in the variable domain were donor residues. [Emphasis by Adair]. In this case, the claims could then be interpreted to cover a structure similar to a "chimeric" antibody comprising a donor variable domain and a human constant region. Such chimeric antibodies were already well known at the priority date.

It plainly is not the intention of the Applicants to claim chimeric antibodies or any similar structures. As can be seen from the description, the superhumanised antibodies of the present invention are compared to the prior art chimeric antibodies. Moreover, the present invention was intended to deal with the problem of chimeric antibodies in that chimeric antibodies were believed to be too "foreign" because of the presence of the complete donor variable domain.

For the above reasons, it is clear that the wording of the claims needed to be changed so that the Applicants' intention of excluding chimeric antibodies was made effective. The language now present in the claims puts this intention clearly into effect.

As to support for this wording, the Examiner is referred firstly to page 16, under the heading "Protocol". It can be seen from this paragraph that the first step in the process involves the choice of an appropriate acceptor chain variable domain. This acceptor domain must be of known sequence. Thus, the protocol starts with a variable domain in which all the residues are acceptor residues. In the sentence bridging pages 16 and 17, it is stated that:

"The CDR-grafted chain is then designed <u>starting from the</u>

basis of the acceptor sequence ". [Emphasis by Adair].

On page 17, in the middle paragraph, it is stated that:

"The positions at which donor residues are to be substituted for acceptor in the framework are then chosen as follows ...."

This again shows that, unless a residue is chosen for substitution, it will remain as in the acceptor sequence.

It must also be borne in mind that the purpose of the invention is to obviate some of the disadvantages of prior art proposals. The proposal of using chimeric antibodies had the disadvantage that they were more "foreign" than desirable. The problem of making CDR-grafted antibodies was that they generally did not provide good recovery of affinity. Thus, the aim of the present invention was to minimise as far as possible the "foreign" nature of the antibody while maximising as far as possible its affinity.

Bearing the passages referred to above and the aim of the invention in mind, it would have been abundantly clear to the skilled person reading the application that as many residues as possible should remain as acceptor residues. If this were not the case, it could hardly be said that the composite chain is based on the acceptor sequence.

The skilled person reading the application can plainly see that certain residues have been considered for changing from acceptor to donor. These are clearly set out in the description. It would be plain to the skilled person that all other residues should not be considered for changing at all. It would therefore be obvious that any residue which is not specified as being under consideration for changing must remain as in the acceptor chain.

It may be that there is no explicit statement in the description that the specified residues should remain as in the acceptor chain. However, the disclosure in a specification is not limited to the explicit disclosure but also includes that which is implicit. It is implicit, in the recitation that the chain is based on the acceptor and that only certain residues are considered for changing, that all non-specified residues must remain as acceptor residues. Subject matter which might be fairly deduced from the disclosure is not new matter. *Acme Highway Products Corp. v. D.S. Brown Co.,* 431 F.2d 1074, 1080, 167 U.S.P.Q. 129, 132-133(6th Cir. 1970), *cert denied,* 401 U.S. 956 (1971).

Another way to look at it.is to consider a different way in which the claim could be drafted. It could be specified that in the composite chain, at least a certain minimum number of residues are donor residues (as in the present claims) and at most a certain maximum number of residues are donor residues. The maximum number would be derived by listing all the residues which are

considered for changing. Such an amendment would have clear explicit basis in the description because all those residues are mentioned as such. However, the effect of such an amendment would be to produce claims of exactly the same scope as the present claims. It can thus be seen that the present claims do not add subject matter but are plainly properly based on the disclosure in the description.

It is therefore submitted that the claims are fully supported by the description, are commensurate in scope with the disclosure in the description, and are properly delimited over the prior art. [Ex. 2010, pp. 3-7].

ADMITTED

34. Adair did not present a newly executed declaration at the time of filing the `261 application but, rather, relied on the inventor declaration from the parent application to satisfy the requirements of 37 C.F.R. § 1.63. (Ex. 2002).

ADMITTED THAT ADAIR RELIED UPON AN INVENTOR DECLARATION FROM A PRIOR APPLICATION.

35. On November 21, 2005, Adair filed its involved application, *i.e.,* U.S. Patent Application No. 11/284,261 ("the `261 Application"). (Ex. 2002).

ADMITTED

36. On November 21, 2005, Adair presented new claim 24 as follows:

Claim 24 (new) 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 . [Ex. 2003, p. 3].

ADMITTED

37. On September 9, 2009 , Adair presented its involved claim 24 in the `261 application, which reads as follows:

Claim 24 (currently amended): 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 . [Ex. 2004, p. 2; Adair Clean Copy of Claims, Paper No . 5, p. 4].

ADMITTED

38. Appendix 3 is a claim chart comparing Adair claim 24 as originally filed in 2005 and Adair involved claim 24.

UNABLE TO ADMIT OR DENY

39. Adair involved claim 24 encompasses a humanized antibody wherein the heavy chain variable domain framework region has any combination of human and non-human amino acid residues at positions 23, 24, 49, 71, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

DENIED -- HAVING ALL HUMAN AMINO ACID RESIDUES AT THESE POSITIONS IS NOT ENCOMPASSED.

40. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at positions 71, 73 and 78 and human amino acids at positions 23, 24, and 49. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

DENIED -- THERE IS NO "HEAVY CLAIM VARIABLE DOMAIN."

41. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at positions 23 and 71 and human amino acids at positions 24, 49, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4).

DENIED -- THERE IS NO "HEAVY CLAIM VARIABLE DOMAIN."

42. Adair involved claim 24 encompasses a humanized antibody wherein the heavy claim variable domain framework region has non-human amino acids at position 23 and human amino acids at positions 24, 49, 71, 73 and 78. (Adair Clean Copy of Claims, Paper No. 5, p. 4.)

DENIED -- THERE IS NO "HEAVY CLAIM VARIABLE DOMAIN."

ADAIR STATEMENT OF ADDITIONAL MATERIAL FACTS

43. The application that issued as U.S. Patent No. 6,407,213 ("the Carter '213 patent") was filed as a national phase of a PCT application filed on June 15, 1992 ("the Carter PCT application"). (Ex. 2001, first page.)

44. The Carter PCT application was filed as a continuation-in-part of Application Serial No. 07/715,272, filed on June 14, 1991 ("the Carter '272 application"). (Ex. 2001, first page.)

45. The PCT Application was filed on December 21, 1990. (Fact 2.)

46. The PCT Application was filed almost six months before the Carter '272 application. (Facts 44 and 45.)

47. The PCT Application was filed almost 18 months before the Carter PCT application. (Facts 43 and 45.)

48. The UK Application was filed on December 21, 1989. (Fact 1.)

49. The UK Application was filed almost 18 months before the Carter '272 application was filed. (Facts 44 and 48.)

50. The UK Application was filed almost 30 months before the Carter PCT application was filed. (Facts 43 and 48.)

51. The PCT Application published on July 11, 1991. (Ex. 2005, first page.)

52. The Carter '272 application was filed less than one month before the PCT Application published. (Facts 44 and 51.)

53. On page 16, lines 23-28, the involved Adair specification reads as follows:

> 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 rationa1e are

given **without prejudice to the generality of the invention as hereinbefore described and defined**.

(Ex. 2002, p. 16, ll. 23-28, emphasis added.)

54. At page 6, lines 31-37, under the heading "Summary of the Invention," the involved Adair specification reads as follows:

> 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, p. 6, ll. 31-37, emphasis added).

55. On page 48, lines 24-27, of the '261 application, it is reported that changes at residues 6, 23, and 24 were important for maintaining a binding affinity similar to that of the murine antibody. (Ex. 2002, p. 48, ll. 24-27; *see also* graft 184 in Figure 11a.)

56. On page 58, lines 1-6, of the '261 application, it is reported that the change of a **single** residue in the heavy chain, residue 73, was sufficient to generate an antibody with binding properties similar to the donor. (Ex. 2002, p. 58, ll. 31-36, emphasis added.)

57. On page 64 of the '261 application, the following is stated:

> It will be appreciated that the foregoing examples are given by way of illustration only and are not intended to limit the scope of the claimed invention. Changes and modifications may be made to the methods described whilst still falling within the spirit and scope of the invention.

(Ex. 2002, p. 64, ll. 14-18.)

58. On page 17, lines 1-5, the involved Adair specification states that

> [i]t will be appreciated that in some cases the donor and acceptor amino acid residues may be identical at a particular position thus no change of acceptor framework residue is required.

(Ex. 2002, p. 17, ll. 1-5.)

59. Claim 1 of the PCT Application does not require that any residues be changed to donor. (Ex. 2005, claim 1, p. 67.)

60. Original claim 1 of the '329 application does not require that any residues be changed to donor. (Ex. 2006, claim 1, p. 67.)

61. The examiner interpreted claim 1 of the '329 application to be anticipated by Riechmann et al. (i.e., Ex. 2011) because the examiner said the antibody of Riechmann et al. had donor residues at positions 6, 49, 76, 88, and 91 of the heavy chain. (Ex. 2038, p. 8.)

62. Riechmann et al. did not disclose changing residues 6, 49, 76, 88, and 91 of the heavy chain to donor. (Ex. 2011, p. 326, col. 1, 1st full paragraph.)

63. The examiner interpreted claim 1 of the '329 application to be anticipated by Queen et al. (i.e., Ex. 2023) because the examiner said the antibody of Queen et al. had donor (murine) amino acids at positions 6, 23, 24, 48, 49, 71, 73, and 78, among others. (Ex. 2038, p. 10.)

64. Queen et al. did not disclose changing residues 6, 23, 24, 39, 71, 73, or 78 of the heavy chain to donor. (Ex. 2023, e.g., Figure 2b.)

65. Claims 66-68, 70-71, 78, and 80-82 of the '213 patent encompass a single residue change at residues 24 or 73 of the heavy chain. (Ex. 2001, claims 66-68, 70-71, 78, and 80-82.)

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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 105,744 (SGL)
Technology Center 1600

_____

NOTICE REGARDING OBJECTIONS TO EVIDENCE
(Re: Evidence Filed With Adair Oppositions 1-2)

NOTICE REGARDING OBJECTIONS TO EVIDENCE

The Board has set an expedited schedule for consideration of Carter Motions 1 and 2. See Paper No. 23.

In the "Order - Authorizing Oppositions - 125(a)" dated June 16, 2010 (Paper No. 73), the Board extended to July 28, 2010, the time period for Carter to file any objections to evidence filed in support of Adair Oppositions 1 and 2.

Adair Oppositions 1 and 2 were filed on July 14, 2010, and were not accompanied by any new exhibits. Accordingly, Carter does not object to the admissibility of the evidence cited in support of Adair Oppositions 1 and 2.

In view of the above, Carter respectfully requests the Board to indicate whether the Board intends to authorize replies to Adair Oppositions 1 and 2, and whether the parties should plan to proceed with the filing of additional motions at Time Period 1 as presently contemplated under the scheduling order entered on April 27, 2010 (Paper No. 23).

The undersigned continues to have scheduled commitments through July 22, 2010.

Respectfully submitted,

July 15, 2010

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CERTIFICATE OF FILING

The undersigned certifies that a copy of the paper entitled **"NOTICE REGARDING OBJECTIONS TO EVIDENCE (Re: Evidence Filed With Adair Oppositions 1-2)"** was filed this 15th day of July, 2010, via Interference Web Portal (https://acts.uspto.gov/ifiling/), with:

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July 15, 2010 /Oliver R. Ashe, Jr./
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the paper entitled **"NOTICE REGARDING OBJECTIONS TO EVIDENCE (Re: Evidence Filed With Adair Oppositions 1-2)"** was served this 15th day of July, 2010, via Interference Web Portal (https://acts.uspto.gov/ifiling/), on the Attorney of Record for Adair:

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Paper No. _____

Filed on behalf of: Parties Carter & Adair

Filed: August 9, 2010

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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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 105,744 (SGL)
Technology Center 1600

_____

JOINT NOTICE OF EXTENSION OF TIME AND REQUEST FOR TELECONFERENCE

JOINT NOTICE OF EXTENSION OF TIME AND REQUEST FOR TELECONFERENCE

Time Period 1 is set to expire on August 9, 2010. (*See* Order - Motion Times - Bd.R. 104(c), Paper No. 23, filed April 27, 2010). In view of the particular circumstances of this interference (Interference No. 105,744) and a related Interference (Interference No. 105,762), the parties are jointly stipulating to extend Time Period 1 to **August 23, 2010**.

Specifically, in the instant interference (the '744 Interference), threshold motions and related oppositions have been filed on an expedited schedule. Time Periods 1-9 have been set for the filing of additional motions and related oppositions and replies. In a recent e-mail communication from the Board, the parties were informed that a decision on the threshold motions will be entered soon.

In the order declaring Interference No. 105,762, noting a relationship between the '744 and '762 Interferences, the Board set an accelerated schedule for the filing of motions lists and an initial teleconference with Administrative Patent Judge. In a recent e-mail communication, the Board indicated that the initial teleconference was cancelled and that an order would follow.

The decision(s) on the threshold motions may affect the substance of any additional motions to be filed in this interference. In view of the circumstances described above and the significant resources associated with the preparation and filing of additional motions, the parties have agreed to extend Time Period 1. In the event decisions on the threshold motions are not entered before **August 16, 2010**, the parties respectfully request a teleconference with the Administrative Patent Judge at her earliest convenience to discuss the status of the case and whether an additional extension of time may be necessary to allow for entry of a decision on threshold motions before Time Period 1.

The attached proposed schedule includes the times for taking action in the motions phase as set forth in the Appendix of the Order - Motion Times - Bd.R. 104(c) (Paper No. 23). The old date for Time Period 1 is crossed out and the new date is inserted by hand.

Respectfully submitted,

August 9, 2010

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Appendix--ORDER - RULE 123(a)
(Times for substantive motions; priority deferred)

Interference 105,744

CARTER THRESHOLD MOTIONS.....**1 June 2010**

ADAIR OPPOSITION, RESPONSIVE MOTIONS.....to be set if needed

TIME PERIOD 1 (all other authorized motions).....~~**9 August 2010**~~ **23 August 2010**
File motions
File (but serve one week later) priority statements

TIME PERIOD 2.....**20 September 2010**
File responsive motions (none authorized at this time)
filed in TIME PERIOD 1

TIME PERIOD 3.....**2 November 2010**
File oppositions to all motions

TIME PERIOD 4.....**14 December 2010**
File all replies

TIME PERIOD 5.....**4 January 2011**
File request for oral argument
File motions to exclude
File observations

TIME PERIOD 6.....**18 January 2011**
File oppositions to motions to exclude
File response to observations

TIME PERIOD 7.....**1 February 2011**
File replies to oppositions to motions to exclude

TIME PERIOD 8.....**8 February 2011**
File exhibits
File sets of motions
File any CD-ROMs

TIME PERIOD 9.....**to be set**
Default oral argument date (if ordered)

CERTIFICATE OF FILING

The undersigned certifies that a copy of the paper entitled **"JOINT NOTICE OF EXTENSION OF TIME AND REQUEST FOR TELECONFERENCE"** attaching revised Appendix to Paper No. 23 was filed this 9th day of August, 2010, via Interference Web Portal (https://acts.uspto.gov/ifiling/), with:

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August 9, 2010 /Oliver R. Ashe, Jr./
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CERTIFICATE OF SERVICE

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August 9, 2010 /Oliver R. Ashe, Jr./
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Paper No. _____

Filed on behalf of: Parties Carter & Adair

Filed: August 23, 2010

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Senior Party
(Application No. 11/284,261),

_____

Patent Interference 105,744 (SGL)
Technology Center 1600

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SECOND JOINT NOTICE OF EXTENSION OF TIME PERIOD 1

SECOND JOINT NOTICE OF EXTENSION OF TIME PERIOD 1

Further to the Joint Notice of Extension of Time and Request for Teleconference (Paper No. 78, filed August 9, 2010), the parties have agreed to extend **Time Period 1** from August 23, 2010, to **September 6, 2010**.

The attached proposed schedule includes the times for taking action in the motions phase as set forth in the Appendix of the Order - Motion Times - Bd.R. 104(c) (Paper No. 23) and the Joint Notice of Extension of Time and Request for Teleconference (Paper No. 78). The old date for Time Period 1 is crossed out and the new date is inserted by hand.

Respectfully submitted,

August 23, 2010

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Appendix--ORDER - RULE 123(a)
(Times for substantive motions; priority deferred)

Interference 105,744

CARTER THRESHOLD MOTIONS.....**1 June 2010**

ADAIR OPPOSITION, RESPONSIVE MOTIONS.....to be set if needed

TIME PERIOD 1 (all other authorized motions).....~~23 August 2010~~ 6 September 2010 ~~9 August 2010~~
File motions
File (but serve one week later) priority statements

TIME PERIOD 2.....**20 September 2010**
File responsive motions (none authorized at this time)
filed in TIME PERIOD 1

TIME PERIOD 3.....**2 November 2010**
File oppositions to all motions

TIME PERIOD 4.....**14 December 2010**
File all replies

TIME PERIOD 5.....**4 January 2011**
File request for oral argument
File motions to exclude
File observations

TIME PERIOD 6.....**18 January 2011**
File oppositions to motions to exclude
File response to observations

TIME PERIOD 7.....**1 February 2011**
File replies to oppositions to motions to exclude

TIME PERIOD 8.....**8 February 2011**
File exhibits
File sets of motions
File any CD-ROMs

TIME PERIOD 9.....**to be set**
Default oral argument date (if ordered)

CERTIFICATE OF FILING

The undersigned certifies that a copy of the paper entitled **"SECOND JOINT NOTICE OF EXTENSION OF TIME PERIOD 1"** attaching revised Appendix to Paper No. 23 was filed this 23rd day of August, 2010, via Interference Web Portal (https://acts.uspto.gov/ifiling/), with:

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August 23, 2010 /Oliver R. Ashe, Jr./
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the paper entitled **"SECOND JOINT NOTICE OF EXTENSION OF TIME PERIOD 1"** attaching revised Appendix to Paper No. 23 was served this 23rd day of August, 2010, via Interference Web Portal (https://acts.uspto.gov/ifiling/), on the Attorney of Record for Adair:

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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
SALLY C. MEDLEY
Administrative Patent Judge

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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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Filed September 13, 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)

ORDER – Miscellaneous – 104(a)

A conference call was held on 9 September 2010 at approximately 2:00 pm.

Participating in the call were:

(1) Oliver Ashe and Jeffrey Kushan for Carter,

(2) Doreen Trujillo for Adair, and

(3) Sally Gardner Lane, Administrative Patent Judge.

The purpose of the call was to discuss the filing of motions in related interference 105762. However, during the call counsel for Adair asked about the time for requesting rehearing for the Decision (Paper 80) and Judgment (Paper 81) entered 2 September 2010. As discussed during the call, because judgment was entered on the basis of the Decision, Adair has 30 days from entry of the judgment to file any request for rehearing. Bd. R. 127(d).

/Sally Gardner Lane/

Administrative Patent Judge

cc (via electronic):

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Paper No:_____
Filed: October 1, 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)

ADAIR REQUEST FOR REHEARING
(regarding Carter Motion 1)

Pursuant to Bd. R. 125(c) and SO 125, Adair requests rehearing of the Board's decision regarding Carter Substantive Motion 1 ("Carter Motion 1"). In its "Order – Decision on Motions" (Paper No. 80, "the Decision"), the Board granted Carter Motion 1 requesting that Adair involved claim 24 be found unpatentable under 35 U.S.C. § 135(b)(1). Judgment was entered September 2, 2010 (Paper No. 81). This request is timely.

Adair contends, as outlined below, that the Board misapprehended and/or overlooked several factual and legal issues in the Decision. The exhibits believed to be overlooked or misapprehended by the Board are identified in Appendix 1.

On page 7, lines 9-10, the Decision states that Carter argues that the pre-critical date claims of Adair include different **material** limitations than those in Adair's involved claim 24, citing Carter Motion 1, at 3. On page 8, lines 3-4, the Decision states that Adair does not dispute that claims reciting a heavy chain and claims reciting a light chain differ **materially**. Carter, however, does not argue that claims reciting a heavy chain and claims reciting a light chain differ materially. Carter observes, rather, that heavy and light chains are different *polypeptides* and that a residue substitution in a light chain is *structurally* different from a residue substitution in a heavy chain (Carter Motion 1, p. 3, ll. 8-17). Notably, the claims of the Carter '213 patent in interference recite changes to residues in the heavy **and** the light chains (see, for example, claim 30 of Ex. 2001).

On page 9, lines 1-5, the Decision contends that Adair did not make the correct comparison under *The Regents of the Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371

Unless otherwise indicated, the same abbreviations as used in the Decision are used herein.

(Fed. Cir. 2006).[2] Neither Carter nor Adair cited *Regents* in their papers (*see* Paper No. 71 -- Carter Motion 1 and Paper No. 75 -- Adair Opposition 1), nor does it appear to be applicable. In *Regents*, the **pre**-critical date claims had been copied from the patent and were canceled and replaced by another claim *after* the critical date. The Board found that the post-critical date claim contained material differences from the pre-critical date claims. The appellant did not challenge the Board's finding of material differences between the post- and pre-critical date claims. The appellant challenged, rather, whether the correct inquiry is whether the pre-critical date claims contain material differences from the post-critical date claims and not whether the pre-critical date claims are to the same invention as the patent claims. *Regents*, 455 F.3d at 1373. In the present case, the pre-critical date claims were not copied from the Carter '213 patent; the **post**-critical date claim, which eventually became Adair involved claim 24, was copied from the patent. Indeed, the court in *Regents* distinguished cases cited by the appellant in which the claims added after the critical date were copied from the patent. *Regents*, 455 F.3d at 1375.

Adair contends that the proper test to be applied to the present facts is that outlined in *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002) and *Corbett v. Chisholm*, 568 F.2d 759 (CCPA 1977). In *Berger*, the issue was whether or not the **pre**-critical date claims contained all material limitations of the later claims which had been copied from the patent. The court found a limitation material because it was added by the **patentee** during prosecution to avoid the prior art.

> Because the prior art applies in like manner to the claims **as copied**, the materiality of a limitation in a claim **copied** to provoke

[2] The Decision did include parallel citations, so Adair has not.

> 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. The material differences test discussed in *Berger,* thus, focuses upon whether all material limitations of the copied **patent** claim necessarily occurred in the pre-critical date claims to determine compliance with 35 U.S.C. § 135(b). Similarly, in *Corbett*, the court observed that

> [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. Neither the Decision, nor Carter, argued that the pre-critical date claims do not contain all material limitations of the Carter '213 patent claims.

Even if *Regents* is applicable, which Adair contends it is not, it did not change the material differences test. *Regents* clearly states that the material differences test is the test discussed in opinions like *Berger*.

> When a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for *section 135(b)(1)*, this court applies the material differences test discussed in opinions like *Berger* to determine if "such a claim" is barred.

Regents, 455 F.3d at 1376. As noted above, 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. Materiality is determined in view of the **patent** claims being copied.

The Federal Circuit does make the following statement in *Regents* in response to California's assertion that the result unfairly denied applicants access to an interference just because their **pre**-critical date claims added **to provoke the interference** lacked written descriptive support:

> … 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 F3d at 1376-77. This statement is cited in the Decision to support requiring that the post-critical date claim in interference be materially the same as the claim that was timely presented (the Decision, p. 10, l. 20 to p. 11, l. 4). This statement from *Regents* is not inconsistent with Adair's arguments regarding materiality, however. If, prior to the critical date, an applicant copies patent claims to provoke an interference and, 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. The claims are no longer to substantially the same invention as required by 35 U.S.C. § 135(b)(1).

Even if the materiality test is as asserted in the Decision, however, the Board did not properly apply the test. The Board did not determine that involved claim 24 is materially different from all pre-critical date claims. Rather, on page 9, lines 6-14, the Decision states that, even considering claims 1 and 16 of the PCT application, it is not convinced that Adair had a pre-critical date claim that does ***not*** differ materially from its involved claim, noting, *inter alia,* that the original claims were rejected under several statutory grounds and then canceled. First, canceled claims, can be relied upon for determining compliance with 35 U.S.C. § 135(b); s*ee* *Corbett*, 568 F.2d at 761 and 765 (pre-critical date claims that were canceled over 15 months after being introduced and 27 months before the patent issued were considered for compliance with 35 U.S.C. § 135(b)). Second, the Board should have to be convinced by Carter, not Adair, that **all** pre-critical date claims differ materially from involved claim 24 in order to grant Carter Motion 1, as Carter bears the burden on this motion (the Decision, p. 3, ll. 19-20). In

contravention of Bd. R. 41.121(e) and SO 121.6, Carter did not compare any pre-critical date claims other than original claims 8 and 16 to involved claim 24 (*see* Carter Motion 1, Appendix 3). Had Carter compared all pre-critical date claims to involved claim 24, the Board might not have overlooked that original pre-critical date claim 2 recites all the residues recited in involved claim 24 – i.e., residues 23, 24, 49, 71, 73, and 78, of the heavy chain (see Ex. 2005, and Appendix 2).

On page 10, lines 3-5, the Decision states that 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. The Decision, however, does not identify any limitations that differ between original claims 1 and 16 and involved claim 24, much less limitations that were necessary to patentability. The Decision apparently assumes that, because original claims 1 and 16 were rejected and involved claim 24 was allowed, limitations must be different and, *a priori*, must be material to patentability. And, again, the burden was upon Carter not only to show that there are differences, but also that any differences were material to patentability. Carter did not show either. Carter conclusorily stated that no pre-critical date claim was identical to or includes the same material limitations as involved claim 24 (Carter Motion 1, Fact 42). Carter dismissed the original pre-critical date claims by arguing that they were unpatentable, and that Adair could not rely upon such claims because they were unpatentable (Carter Motion 1, p. 9, ll. 8-11). Regarding the non-original pre-critical date claims, Carter simply argued that they were not supported by the specification for essentially the same reasons it asserted that involved claim 24 was not supported by the specification in Carter Motion 2 -- an argument that was clearly not accepted by the Board as it denied Carter Motion 2 – Paper No. 72 (the Decision, p. 17, ll. 5-6).

On page 10, lines 5-7, the Decision states that Adair did not point to any other pre-critical date claim that is identical to or includes the same material limitations as involved claim 24. Adair is aware of no case law requiring that the pre- and post-critical date claims be identical, nor does the Decision cite any. Further, requiring that Adair identify such a claim improperly shifts the burden on the motion to Adair, even though Carter bears the burden of proof on the motion.

On page 10, lines 5-10, the Decision states that Adair did not admit or deny Carter's Fact 42 alleging that no pre-critical date claim was identical to or includes the same material limitations as involved claim 24. In view thereof, the Decision adopts Carter Fact 42 as its own Finding of Fact 6 (the Decision, p. 4, l. 21 through p. 5, l. 1). The Decision has effectively penalized Adair for stating that it was unable to admit or deny a fact. The Standing Order, however, provides for a party to state that it is unable to admit or deny a fact, and does not state that doing so is effectively an admission of that fact. *See* SO 122.4.2.1. Regardless, as noted above, Carter did not compare any pre-critical date claims other than original claims 8 and 16 to involved claim 24 (*see* Carter Motion 1, Appendix 3), much less identify which claims were or were not identical, or which limitations were material. Under the circumstances, Adair felt the most appropriate response was to say that it was unable to admit or deny the statement, apparently to its detriment.

Finally, on page 10, lines 10-12, the Decision states that Adair could have, but did not seek, authorization to file a motion to add a pre-critical date claim that interferes with the Carter claims. As noted in *Berger*, however, the test whether or not claims interfere is not the proper test under section 135(b). *See Berger*, 279 F.3d at 982. Regardless, Adair would have to certify that it was not aware of any reason why the claim it is adding is not patentable. SO 208.5.1 and

Bd. R. § 41.208 (c). And, as the Decision noted, the original pre-critical date claims were rejected and canceled (the Decision, p. 9, ll. 6-14). Thus, it would clearly have been futile for Adair to attempt to add an original pre-critical date claim. It is not clear what the Decision concluded regarding the non-original pre-critical date claims, other than that it adopted Carter's Fact 42 as a finding of fact because Adair did not outright deny it; there was no other analysis of such claims in the Decision.

Conclusion

The Decision contains several factual and legal issues misapprehended or overlooked by the Board. Adair requests that the Decision regarding Carter Motion 1 be reconsidered and that Carter Motion 1 be denied.

Respectfully submitted,

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APPENDIX 1

Ex. 2001 -- U.S. Patent No. 6,407,213 to Carter ***et al.,*** issued June 18, 2002.

Ex. 2005 – PCT Application No. PCT/GB90/02017 to Adair *et al.,* filed December 21, 1990, published as WO 91/09967 on July 11, 1991.

APPENDIX 2

Claims from the PCT Application (Ex. 2005)	Adair Claim 24
1. 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. 2. A CDR grafted heavy chain according to Claim 1 comprising donor residues at **positions 23, 24, 49, 71, 73 and 78,** or at positions 23, 24 and 49. 16. 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.	Claim 24: 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.

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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

[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
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Administrative Patent Judge

/ss/ Richard Torczon
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Paper No. _____
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UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
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_____

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 105,744 (SGL)
Technology Center 1600

_____

CARTER NOTICE OF FILING OF A NOTICE OF CROSS APPEAL
(Appeal to the Court of Appeal for the Federal Circuit)

CARTER NOTICE OF FILING OF A NOTICE OF CROSS APPEAL

Notice is hereby given to the Director of the United States Patent and Trademark Office and to the Board of Patent Appeals and Interferences that Carter filed a Notice of Cross Appeal to the Court of Appeals for the Federal Circuit relating to the Order - Decision on Motions, Paper No. 80, entered on August 30, 2010, and the Judgment, Paper No. 81, entered on September 2, 2010, in the above-captioned interference. A copy of the Notice of Cross Appeal is attached.

Respectfully submitted,

January 18, 2011

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CERTIFICATE OF FILING

The undersigned certifies that a copy of the paper entitled **"CARTER NOTICE OF FILING OF A NOTICE OF CROSS APPEAL"** was filed this 18th day of January, 2011, in the following manner:

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January 18, 2011 /Oliver R. Ashe, Jr./
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the paper entitled **"CARTER NOTICE OF FILING OF A NOTICE OF CROSS APPEAL"** was served this 18th day of January, 2011, via Interference Web Portal (https://acts.uspto.gov/ifiling/), on the Attorney of Record for Adair:

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January 18, 2011 /Oliver R. Ashe, Jr./
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United States Court of Appeals for the Federal Circuit

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

Appellants,

v.

NOTICE OF CROSS APPEAL

PAUL J. CARTER AND LEONARD G. PRESTA,

Appellees-Cross Appellants.

PAUL J. CARTER and LEONARD G. PRESTA hereby appeal to the Court under 35 U.S.C. § 141 for review of the following Order and Judgment entered by the Board of Patent Appeals and Interferences ("the Board") in Interference No. 105,744:

- Order - Decision on Motions, Paper No. 80, entered on August 30, 2010 (to the extent the Board denied Carter Substantive Motion 2 for judgment that Adair claim 24 is unpatentable to Adair under 35 U.S.C. § 112, first paragraph, for lack of written description); and
- Judgment - Merits - Bd.R. 127, Paper No. 81, entered on September 2, 2010 (to the extent the Board did not also enter judgment against Adair claim 24 based on the relief requested in Carter Substantive Motion 2).

Copies of the Order and Judgment are enclosed.

A docketing fee in the amount of $450.00 is provided herewith.

Respectfully submitted,

January 18, 2011

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Clerk of Court
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Washington, D.C. 20439

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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
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Junior Party
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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
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/ss/ Sally C. Medley
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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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Paper No:_____
Filed: January 19, 2011

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)

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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/Doreen Yatko Trujillo/
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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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Date: January 4, 2011

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
Administrative Patent Judge

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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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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
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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 s*ection 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,

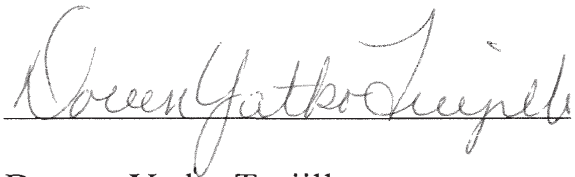
Adair had failed to provide a sufficient comparison to show that it is materially the same as the copied claim (A26). Adair is not sure what more it could have done. Adair argued that claim 2 of the PCT application recited all the residues recited in Adair claim 24, and included a chart in the appendix 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
Administrative Patent Judge

/ss/ Sally C. Medley
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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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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

---

UNOPPOSED MOTION TO DISMISS CARTER'S CROSS-APPEAL

Oliver R. Ashe, Jr.
ASHE, P.C.
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Rachel H. Townsend
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000

Attorneys for Cross-Appellants, Carter *et al.*

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.

In accordance with Rule 42(b), Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA ("Carter") move the Court to dismiss Carter's cross-appeal filed on January 18, 2011, and assigned Appeal No. 2011-1213.

In support of this motion, Carter states as follows:

1. Carter filed two substantive motions with the Board of Patent Appeals and Interferences, which asserted "threshold" issues that if decided in Carter's favor would end the interference. The first motion requested that Adair claim 24 be found to be barred under 35 U.S.C. § 135(b)(1). The second motion requested that Adair claim 24 be found unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description. On August 30, 2010, the Board granted Carter's first motion concluding that Adair's involved claim 24 is barred under 35 U.S.C. § 135(b)(1). The Board denied Carter's second motion. The Board entered judgment against Adair on September 2, 2010, "[b]ecause Adair no longer has an interfering claim that is not barred under 35 U.S.C. § 135(b)." Adair's request for rehearing, filed October 1, 2010, was denied by the Board on November 5, 2010.

2. On January 4, 2011, Appellants JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE ("Adair") filed its notice of appeal of the Board's adverse decision that its claim 24 was barred under 35 U.S.C. § 135(b).

3. On January 18, 2011, Carter filed a notice of cross-appeal of the Board's adverse decision denying Carter's motion that Adair's claim 24 was unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description.

4. Adair requested and was granted a twenty-five day extension of time extending the time to file its principal brief from April 18, 2011, to May 13, 2011. Adair filed its principal brief on May 13, 2011.

5. On March 24, 2011, this Court issued a precedential order in *Aventis Pharma S.A. v. Hospira,* Nos. 2011-1018, -1047 (Fed. Cir. March 24, 2011). In that order, the Court held that Apotex's additional claims for invalidity and claims of non-infringement to the same claims did not expand the scope of the judgment in Apotex's favor and thus were improper grounds for cross-appeal. Slip op. at 4-5. The Court did go on to note, however, that Apotex could "consistent with our practice and precedent, raise these arguments in its appellees' brief if it so chooses." *Id.* at 5.

6. The *Aventis* order does not address the specific circumstance wherein a claim has been held to be barred under 35 U.S.C. § 135(b) but a motion asserting the unpatentability of the same claim under 35 U.S.C. § 112, first paragraph, has been denied. Nevertheless, in view of the Court's concern expressed in *Aventis* as to whether an issue on cross-appeal would expand the scope of the judgment, Carter withdraws its cross-appeal relating to the issue of whether Adair's claim 24

is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description. The parties agree that this motion does not preclude Carter from raising the issue of the unpatentability of Adair claim 24 under 35 U.S.C. § 112, first paragraph, in its responsive brief in Appeal No. 2011-1212 as an alternative ground for affirmance of the Board's entry of judgment against Adair.

7. Adair consents to the withdrawal of the cross-appeal and each party has agreed to bear its own costs on the cross-appeal.

For the foregoing reasons, Carter's cross-appeal should be dismissed. A proposed order with service list is attached.

Respectfully submitted,

June 9, 2011

Oliver R. Ashe, Jr.
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Jeffrey P. Kushan
Rachel H. Townsend
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
Attorneys for Cross-Appellants, Carter *et al.*

CERTIFICATE OF FILING

The undersigned certifies that an original and three copies of the paper entitled "**UNOPPOSED MOTION TO DISMISS CARTER"S CROSS-APPEAL**" was filed this 9th day of June, 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

6-9-11
Date

Oliver R. Ashe, Jr.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the paper entitled "**UNOPPOSED MOTION TO DISMISS CARTER"S CROSS-APPEAL**" was served this 9th day of June, 2011, by sending in the following manner:

VIA INTERFERENCE WEB PORTAL(https://acts.uspto.gov/ifiling/):

Doreen Yatko Trujillo, Esq.
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VIA FIRST CLASS MAIL (Postage pre-paid):

The Office of Solicitor
United States Patent and Trademark Office
P.O. Box 15667
Arlington, VA 22215

6-9-11
Date

Oliver R. Ashe, Jr.

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

ORDER

Upon consideration of the Unopposed Motion to Dismiss Carter's Cross-Appeal filed by Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA,

IT IS ORDERED THAT:

1) The unopposed motion be GRANTED, and the Clerk of the Court dismiss the cross-appeal assigned Appeal No. 2011-1213.

2) Each side shall bear its own costs.

FOR THE COURT:

Date: _____ _____

Copies to:

Oliver R. Ashe, Jr.
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Reston, VA 20190
Tel.: 703-467-9001
Counsel for Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA

Doreen Yatko Trujillo, Esq.
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Tel.: 215-665-5593
Counsel for Appellants JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE

The Office of Solicitor
United States Patent and Trademark Office
P.O. Box 15667
Arlington, VA 22215

The Board of Patent Appeals and Interferences
Madison Building East, 9th Floor
600 Dulany Street
Alexandria, VA 22314
Tel.: 571-272-9797

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

---

UNOPPOSED MOTION OF CROSS APPELLANTS, PAUL J. CARTER AND LEONARD G. PRESTA, FOR A THIRTY-DAY EXTENSION OF TIME TO FILE ITS OPENING BRIEF

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Rachel H. Townsend
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Washington, DC 20005
(202) 736-8000

Attorneys for Cross-Appellants, Carter *et al.*

June 15, 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 15, 2011

Oliver R. Ashe, Jr.

UNOPPOSED MOTION OF CROSS APPELLANTS, PAUL J. CARTER AND LEONARD G. PRESTA, FOR A THIRTY-DAY EXTENSION OF TIME TO FILE ITS OPENING BRIEF

Pursuant to Fed. R. App. P. 26(b), Cross-Appellants PAUL J. CARTER AND LEONARD G. PRESTA ("Carter") respectfully requests that this Court grant a thirty (30) day extension of time to and including July 27, 2011, within which to file its opening brief in the above-identified case.

The date that Carter's opening brief is currently due is June 27, 2011. Carter has not previously sought any extension of time in this appeal and is filing this motion at least seven days before the brief due date. Counsel for JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE has represented that it does not oppose this motion.

There is good cause for this motion as explained below. Carter's lead attorney on this appeal, Oliver R. Ashe, Jr., is lead and backup lead counsel on five interference proceedings presently before the Board of Patent Appeals and Interferences ("the Board"). Two of these interference proceedings are in fully active motions phases and the schedules are not amenable to significant alterations. Mr. Ashe is responsible for preparing a number of motions to be filed at the Board, including motions due on Wednesday, June 15, 2011, in Interference No. 105,792, motions due on June 24, 2011, in Interference No. 105,771, and responsive motions due on July 15, 2011, in Interference No. 105,771. In addition, due to

longstanding plans for a family vacation, Mr. Ashe will be away from the office from June 25, 2011, through July 10, 2011.

Additionally, one of Carter's other appellate counsel, Jeffery P. Kushan, has a variety of professional commitments that has limited and will continue to limit the time that he is able to devote to the assistance of the preparation and review of Carter's brief. Mr. Kushan is one of the attorneys responsible for preparing and filing expert reports on July 1, 2011 in a case docketed in the District of Delaware. In addition, Mr. Kushan has a longstanding speaking engagement on June 21. And due to a longstanding professional commitment and planned vacation, Mr. Kushan will be away from the office from June 22 through June 28.

Accordingly, Carter needs additional time to prepare its brief. For the purposes of Fed. Cir. R. 27(a)(8), it is not believed that any of the above facts are subject to dispute. However, for the purposes of Fed. Cir. R. 26(b)(5), Carter hereby submits declarations of counsel showing good cause for the extension.

For the reasons set forth herein, it is respectfully requested that Carter's unopposed motion to extend the due date for its brief in the above appeal by thirty (30) days to and including July 27, 2011, be granted.

A proposed order granting the relief requested in this motion with service list is attached.

Respectfully submitted,

June 15, 2011

Oliver R. Ashe, Jr.
ASHE, P.C.
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Reston, VA 20190
(703) 467-9001

Jeffrey P. Kushan
Rachel H. Townsend
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
Attorneys for Cross-Appellants, Carter *et al.*

CERTIFICATE OF FILING

The undersigned certifies that an original and three copies of the paper entitled "**UNOPPOSED MOTION FOR CROSS APPELLANTS, PAUL J. CARTER AND LEONARD G. PRESTA, FOR A THIRTY-DAY EXTENSION OF TIME TO FILE ITS OPENING BRIEF** " was filed this 15th day of June, 2011, by Hand-Delivery, to:

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

6-15-11
Date

Oliver R. Ashe, Jr.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the paper entitled "**UNOPPOSED MOTION FOR CROSS APPELLANTS, PAUL J. CARTER AND LEONARD G. PRESTA, FOR A THIRTY-DAY EXTENSION OF TIME TO FILE ITS OPENING BRIEF**" was served this 15th day of June, 2011, by sending in the following manner:

VIA INTERFERENCE WEB PORTAL(https://acts.uspto.gov/ifiling/):

Doreen Yatko Trujillo, Esq.
Cozen O'Connor P.C.
1900 Market Street, 7th Floor
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600 Dulany Street
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Tel.: 571-272-9797
Fax: 571-273-0042
E-mail: BoxInterfernces@USPTO.GOV

6-15-11
Date

Oliver R. Ashe, Jr.

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

ORDER

Upon consideration of the Unopposed Motion for Extension of Time filed by Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA,

IT IS ORDERED THAT:

1) The unopposed motion be GRANTED, and the Clerk of the Court note this extension on the docket.

2) The principal brief of Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA shall be due on July 27, 2011.

FOR THE COURT:

Date: _____ _____

Service List:

Oliver R. Ashe, Jr.
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11440 Isaac Newton Square North
Suite 210
Reston, VA 20190
Tel.: (703) 467-9001
Counsel for Cross Appellants, Carter *et al.*

Doreen Yatko Trujillo, Esq.
Kyle Vos Strache, Esq.
Cozen O'Connor P.C.
1900 Market Street, 7th Floor
Philadelphia, PA 19103
Tel.: 215-665-5593
Counsel for Appellees, Adair *et al.*

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Madison Building East, 9th Floor
600 Dulany Street
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Tel.: 571-272-9797

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

Declaration of Oliver R. Ashe, Jr.

1. I am lead counsel for Cross-Appellants PAUL J. CARTER and LEONARD G. PRESTA ("Carter").

2. This appeal was docketed in this Court on February 15, 2011, which made Appellants JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE ("Adair")'s opening brief due on April 18, 2011. Adair requested and was granted an extension of time in which to file its opening brief. Adair filed that brief on May 13, 2011. Based on the May 13 filing of Adair's brief, Carter's brief is due on June 27, 2011.

3. I am lead and backup lead counsel on five interference proceedings presently before the Board of Patent Appeals and Interferences ("the Board"). Two of these interference proceedings are in fully active motions phases and the schedules are not amenable to significant alterations. I am responsible for preparing a number of motions to be filed at the Board, including motions due on Wednesday, June 15, 2011, in Interference No. 105,792, and motions due on June 24, 2011, in Interference No. 105,771, and responsive motions due on July 15, 2011, in Interference No. 105,771. In addition, due to longstanding plans for a family vacation, I will be away from the office from June 25, 2011, through July 10, 2011.

4. While significant efforts have been made to avoid having to seek an extension in this case, it has now been determined that an extension of time of thirty (30) days to and including July 27, 2011, would allow adequate time for me to coordinate the drafting, reviewing and filing of Carter's brief.

Pursuant to 29 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct.

June 15, 2011

Oliver R. Ashe, Jr.

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.

Declaration of Jeffrey P. Kushan

1. I am co-counsel for Cross-Appellants PAUL J. CARTER AND LEONARD G. PRESTA ("Carter").

2. This appeal was docketed in this Court on February 15, 2011, which made Appellants JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE ("Adair") opening brief due on April 18, 2011. Adair requested and was granted an extension of time in which to file its opening brief. Adair filed that brief on May 13, 2011. Based on the May 13 filing of Adair's brief, Carter's brief is due on June 27, 2011.

3. Various professional commitments have limited and will continue to limit the time that I am able to devote to the assistance of the preparation and review of

Carter's opening brief. Among other matters, I am counsel for Alza Corporation and Ortho-McNeil-Janssen Pharmaceuticals, Inc. in *Alza Corp. v. Kremers Urban, LLC.*, CA No. 10-23-LPS (D. Del.) and am one of the attorneys responsible for preparing and filing expert reports in that case on July 1, 2011. I also have a speaking engagement on June 21 for which I will be out of the office. In addition, due to a longstanding professional commitment and family vacation, I will be away from the office from June 22 through June 28.

4. As a result of these and other commitments, and despite diligent efforts, it will not be possible for me to assist in the preparation and filing of Carter's opening brief in this matter by June 27, 2011. An extension of time of thirty (30) days to and including July 27, 2011, would allow adequate time for counsel to coordinate the drafting, reviewing and filing of Carter's brief.

Pursuant to 29 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct

June 15, 2011

Jeffrey P. Kushan

NOTE: This order is nonprecedential.

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,
Appellees.

2011-1212
(Interference No. 105,744)

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

JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, AND JOHN SPENCER EMTAGE,
Appellees,

v.

PAUL J. CARTER AND LEONARD G. PRESTA,
Appellants.

2011-1213
(Interference No. 105,744)

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

ORDER

Upon consideration of the cross-appellants' unopposed motion for voluntary dismissal of cross-appeal, 2011-1213, pursuant to Fed. R. App. P. 42(b),

IT IS ORDERED THAT:

The motion is granted. The revised caption in 2011-1212 is reflected above.

(2) Each side shall bear its own costs in 2011-1213.

FOR THE COURT

JUL 6 2011
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Doreen Yatko Trujillo, Esq.
Oliver R. Ashe, Jr., Esq.

s24

ISSUED AS A MANDATE (as to 2011-1213 only): JUL 6 2011

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

JUL 06 2011

JAN HORBALY
CLERK

CERTIFIED COPY
I HEREBY CERTIFY THIS DOCUMENT
IS A TRUE AND CORRECT COPY
OF THE ORIGINAL ON FILE.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

By: Date: 7/6/11

2011-1212
(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.

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

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

Doreen Yatko Trujillo
(Counsel of Record)
Kyle Vos Strache
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Philadelphia, PA 19103
215-665-2000

Attorneys for Appellants
John Robert Adair, Diljeet Singh Athwal,
And John Spencer Emtage

Dated: August 15, 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

August 15, 2011
Date: August 15, 2011

Doreen Yatko Trujillo
Signature of counsel

Doreen Yatko Trujillo
Printed name of counsel

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes & Other Authorities:

INTRODUCTION

Carter dedicated over seven pages of its 57-page brief (twice as long as Adair's principal brief) arguing, essentially, that Adair's claims should be limited by its specification, and that the specification requires multiple framework residues to be changed to donor, i.e., to be non-human (Red Br. 11-18). Adair is unsure why Carter dedicated such a major portion of its brief to an argument not relevant to the issues on appeal. Nonetheless, Carter is misrepresenting Adair's specification. Adair's specification is not as limiting as Carter alleges – the specification does not require multiple framework residues to be changed (A565). Carter is relying upon what is clearly delineated as a "preferred" protocol in arguing that the specification is so limited (Red Br. 12; A576). Further, *In re* Berger, 279 F.3d 975 (Fed. Cir. 2002) disapproves of focusing upon the specification for satisfying *§ 135(b)*. *Id.*, at 983.

Citing an irrelevant patent issued to Adair, Carter also advances the disingenuous argument that changing multiple residues to donor was necessary for Adair to overcome the prior art (Red Br. 18). But Carter's claims do not recite changing multiple residues (A91-3). If the recitation of multiple residues was not necessary for Carter's claims to overcome the prior art, then it is difficult to see how it would be necessary for Adair claim 24.

Neither of the foregoing arguments is relevant to the basis for this appeal.

I. The Basis For This Appeal

The basis for this appeal is the correct interpretation of 35 U.S.C. § 135(b). Specifically, does *§ 135(b)* require applicants to show, in an interference based upon a claim that was submitted post-critical date, not only that the claim has pre-critical date support for its post-critical date identity with a claim of the patent, but also an additional requirement, as Carter and the Board allege, that the claim does not differ from the pre-critical date claim in virtually any respect? By presuming that any change to pre-critical date claims is material and suggesting (repeatedly) that Adair could have moved to add claims **identical** to pre-critical date claims in the involved application, the Board is essentially requiring a showing that the post-critical date claim does not differ from the pre-critical date claim in any respect, thereby setting forth a standard that is not only inconsistent with legal precedent, but is also impossible for applicants to meet.

As anyone who has prosecuted an application before the USPTO[1] knows, particularly in the field of biotechnology, originally-filed claims are rarely, if ever, allowed. Indeed, if they are, applicants are concerned that they did not claim broadly enough. Thus, the fact that an applicant chooses to amend the claims upon rejection, or even cancel them in favor of different claims, is not a concession of unpatentability *per se*, particularly for applications filed after June 7, 1995, but

[1] Unless otherwise indicated, the same abbreviations as were used in the principal brief are used here.

more a reflection of a desire to get allowable claims in a reasonable time frame. An appeal of a rejection can take years to be resolved, particularly if the appeal has to be taken to this Court.

II. 35 U.S.C. § 135(b) Does Not Require An Additional Comparison Between Pre- And Post-Critical Date Claims Without Reference To The Patent Claims Being Copied For Interference

Adair contends that this Court did not impose an additional requirement in *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 pre- and post-critical date claims do not differ from each other in any respect, irrespective of whether or not both contain all material limitations of the patent claim. In *Regents*, this Court stated that *§ 135(b)* prohibits unsupported post-critical date **identity** with a **patent** claim, that one must show pre-critical date support for the post-critical date **identity** between the post-critical date claim in interference and a **patent** claim, and that this demonstration entails a comparison between the pre- and post-critical date claims. *Id.*, at 1375, emphasis added. Accordingly, the pre-critical date claim must have all material limitations of the post-critical date claim, with materiality being assessed in view of the patent claim. This analysis is all that the precedent cited throughout *Regents*, i.e., *Berger*, 279 F.3d 975 and *Corbett v. Chisholm*, 568 F.2d 759 (CCPA 1977), required. In *Berger*, a limitation added by the patentee was considered material.

> The Board found the "circumferential groove" limitation to be material because it was added by Muller [the patentee] during prosecution to avoid prior art. We agree with the Board's determination of materiality.

Berger, 279 F.3d at 982. Similarly, in Chisholm, materiality was assessed in view of the patent claim.

> Turning to a comparison of Chisholm patent claim 1 and claims 24-27, we agree with the conclusion of the board that these claims, even considered as a group, do not recite Chisholm's claimed squeezing step (b). Corbett does not seriously contend that this is not a material limitation, that is, necessary to patentability. . . There being a material limitation of the copied claim not present in Corbett's claims 24-27, they cannot be said to be directed to substantially the same invention.

Corbett, 568 F.2d at 765-66. The pre-critical date claim does not need to have all limitations of the post-critical date claim, then, just those limitations that were material to the **patented** claim.

Indeed, every express limitation is not material under *§ 135(b)*. *Stalego v. Heymes*, 263 F.2d 334, 339 (CCPA 1959). A review of *Berger* reveals that the "circumferential groove" was not the only difference between the post-critical date claim that was copied from the Muller patent and the pre-critical date claim. The pre-critical date claim also did not contain a recitation of a pull tab. *Berger*, 279 F.3d 977-78.

When the post-critical date claim contains all material limitations of the patented claim the comparison becomes, in essence, a comparison between the pre-

critical date claims and the patent claims. *See Berger*, 279 F.3d at 982-83 and *Corbett*, 568 F.2d at 763,765-66. The Court in *Regents* also stated, however, that there is a distinction between comparing pre- and post-critical date claims with one another and comparing pre-critical date claims with the patented claims. *Regents*, 455 F.3d at 1375. The Board, and Carter, has interpreted this statement in *Regents* to mean that there is an additional requirement that the pre-critical date claims contain, essentially, all the limitations of the post-critical date claims, and *vice versa*, irrespective of whether both contain all material limitations of the patent claims. Adair, however, cannot reconcile this interpretation with the purpose of *§ 135(b)*, nor the Court's statements in *Regents* regarding the purpose of *§ 135(b)*, i.e., prohibiting unsupported post-critical date identity with the patent claim, nor the Court's repeated references to *Berger* and *Corbett*. *Regents*, 455 F.3d 1374-75.

An alternative interpretation proffered by Adair in this interference 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, the applicant should not be allowed in the interference, as the claims are no longer to substantially the same invention (Br. 14). Under such circumstances, it would not be sufficient to compare the pre-critical date claims to the patent claims alone. Consistent with this view, the Court distinguished cases in which the post-critical date claims were the ones copied

from the patent. *Regents*, 455 F.3d at 1375.

This interpretation seems to be the most consistent with the whole of the Court's decision but, unfortunately, it is not consistent with the underlying facts as Adair interprets them. A review of the underlying decision of the Board in *Regents* suggests that the post-critical date claim had all the material limitations of the patented claim. *Univ. of Iowa Res. Found. v. Regents of the Univ. of Cal.,* Interf. No. 105,171, slip op. at 3 and 6 (B.P.A.I. March 10, 2005) (Board Decision) Perhaps, however, the Court took the appellant in *Regents* at its word that there were material differences between the post- and pre-critical date claims, and assumed that the post-critical date claims were no longer to the same invention as the patent claims.

Assuming Adair's alternative interpretation is correct, *Regents* is not applicable to the current facts. Adair first requested this interference post-critical date. Even if applicable, Adair maintains that *Regents* did not create an additional test for materiality completely divorced from the patent claims for purposes of compliance with *§ 135(b)*.

Carter argues, incredulously, that this Court found the limitations of the patent claims to be irrelevant in *Regents* because "the relevant question for the issue of repose is whether the later claim is entitled to the effective date of the earlier claim . . . which is essential to establishing that the *same* interference could

have been declared earlier" (Red Br. 43, emphasis in original). Adair questions how the limitations of the patent claims can ever be irrelevant under a statute that requires that a claim that is to substantially the same subject matter as a claim of an issued **patent** be submitted within a specified time frame. 35 U.S.C. § 135(b). Further, *§ 135(b)* does not require that the **same** interference could have been declared earlier, just that **an** interference could have been declared earlier.

Adair contends that both Carter and the Board are confounding the analysis for determining effective filing date for purposes of 35 U.S.C. § 120 with the analysis for determining effective filing date for purposes of 35 U.S.C. § 135(b). But these sections of the Patent Statute serve distinct purposes and have very different requirements. This distinction was recognized in *Berger* which refers to "the earlier effective filing date of those prior claims **for purposes of satisfying 35 U.S.C. § 135(b)**." *Berger*, 279 F.3d at 982 (emphasis added). For example, *§ 120* allows an application for patent to rely upon the filing date of an earlier filed application if the invention is disclosed in the earlier application in the manner provided by the first paragraph of 35 U.S.C. § 112. 35 U.S.C. § 120. Accordingly, under *§ 120*, one must show, *inter alia*, written descriptive support for the recitations in the claims in earlier applications, and one can look to the specification for such support. Contrastingly, *§135(b)* makes no reference to the first paragraph of 35 U.S.C. § 112, nor to the benefit of a filing date, and focuses

upon the claims alone. All that *§ 135(b)* requires is that a claim that is to substantially the same subject matter, not exactly the same subject matter, as a claim of the patent be made prior to one year from the date the patent was granted. 35 U.S.C. § 135(b). The Board and Carter, however, are requiring applicants to show, allegedly under *§ 135(b)*, written descriptive support for all recitations in the post-critical date claims in the pre-critical date claims themselves.

One source of the confusion may be the apparent discrepancy in the various reported versions of a statement in *Berger*, 279 F.3d at 982. The Lexis® and Westlaw® electronic databases report the statement as the following:

> This is a distinctly different question from whether claims made for purposes of interference by different parties are directed to **interfering** subject matter.

Other electronic databases, as well as the book version of the reporter, report the statement as the following:

> This is a distinctly different question from whether claims made for purposes of interference by different parties are directed **to the same or substantially the same** subject matter.

The differences between the two are highlighted in bold. Notably, the immediately preceding sentence in *Berger* sets forth what must be shown under *§ 135(b)*. *Id.*, 279 F.3d at 981-2. As discussed above, *§ 135(b)* recites the language "the same or substantially the same subject matter." 35 U.S.C. § 135(b). Adair contends that the correct version is the first one because interfering subject matter under (prior)

37 C.F.R. § 1.601 was being distinguished from the requirements under *§ 135(b)* in *Berger*. *Id.* Under the latter version, showing that claims are to the same or substantially the same subject matter is being distinguished from showing that claims are to the same or substantially the same subject matter.

III. Even If An Additional Comparison Under *§135(b)* Is Required, Adair Claim 24 Satisfies It

As the Board, and Carter, repeatedly asserted, a limitation that is necessary to patentability is material (see, for example, Red Br. 36). Adair claim 24, having been indicated as allowable, is presumptively patentable (Red Br. 26). If Adair claim 24 is lacking limitations from the earlier claims, then, those limitations could not have been material. Regardless, as Adair argued in its request for rehearing, claim 2 of the PCT application recites all the residues recited as alternatives in Adair claim 24 (Br. 14; A431, A435). As shown in the appendix to Adair's request for rehearing, claim 16 of the PCT application, as depending from claim 2 of the PCT application, thus, contains all material limitations of Adair claim 24, and *vice versa*.[2] The Board declined to consider claim 2 of the PCT application,

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[2] Carter also argues that the Board noted that Adair did not make a sufficient comparison to show that claim 2 is materially the same as the copied claim, evidently in reference to claim 66 of the Carter patent (Red Br. 24). In its initial decision, however, the Board argued that Adair was not to compare its pre-critical date claims to the patent claims under *Regents* (A9). Regardless, if Adair claim 24 contains all material limitations of claim 66 of the Carter patent, which neither the Board nor Carter has argued to the contrary, and claim 16 of the PCT application, as depending from claim 2, contains all material limitations of Adair claim 24,

however, citing a rule related to *ex parte* appeals, not interferences (A26).

In defense of the Board's declination, Carter asserts that Adair has been prosecuting this portfolio for over 14 years and had ample opportunity to explain why claim 2 provided the requisite pre critical date support under *§ 135(b)* (Red Br. 51). Carter's assertion is flawed. Adair had only been trying to provoke an interference with the Carter patent since November 21, 2005 (Br. 2-3). Adair would have had no reason to raise the issue before then. Further, as Adair has repeatedly pointed out, the rules do not require Adair to show compliance with *§ 135(b)* to provoke an interference (Br. 4-5). Carter keeps faulting Adair for not raising an issue that Adair was not required to raise. Notably, nothing prevented the USPTO from raising *§135(b)* as a basis for rejection during that five-year period. *See Berger*, 279 F.3d at 981.

Carter also asserts the Adair's submission of arguments regarding claim 2 of the PCT application were belated (Red Br. 52-3). Carter notes that the Board's Standing Order explains that the Board will not consider evidence presented belatedly in a reply (Red Br. 52). Carter is completely disregarding that the burden was on Carter, as the movant, to make out a *prima facie* case, not on Adair. All Adair needed to do in its opposition was address the arguments raised by Carter. Carter did not cite *Regents* in its motion to support its arguments that Adair claim

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claim 16 of the PCT application, as depending from claim 2, must contain all material limitations of claim 66 of the Carter patent.

24 differed materially from Adair's non-original, pre-critical date claims (A308). In its opposition, then, Adair focused upon arguing that Carter was applying the incorrect materiality test (372). *Regents* was first raised by the Board in its decision (A6). Adair's first chance to address the Board's interpretation of *Regents*, thus, was in its request for rehearing.

Carter also argues that 37 C.F.R. § 41.125(c)(3) prevents a party from raising a matter on rehearing that was not previously addressed by requiring a party to show all matters believed to have been overlooked and to show where the matter was previously addressed in the motion, opposition, or reply (Red Br. 52). First, the Board did not raise this section of the regulations in its decision. Second, Adair complied with 37 C.F.R. § 41.125(c)(3). Adair pointed out that the Board had overlooked claim 2 of the PCT application because Carter failed to meet its burden of addressing each pre-critical date claim in its motion, which Adair had argued in its opposition (A430-1; A370-1).

Regardless, the Board did not raise the Standing Order or 37 C.F.R. § 41.125(c)(3) when it declined to consider claim 2 of the PCT application. Rather, the Board cited a rule relating to *ex parte* appeals (A26). Adair pointed out this further legal error in its brief (Br. 27). Carter faults Adair for not arguing that the Board's declination was arbitrary or unreasonable or otherwise an abuse of discretion (Red Br. 51). Adair did not make such arguments because Adair

contends it was legal error for the Board to apply the wrong regulation. Nonetheless, an abuse of discretion can be established if the exercise of discretion is based upon **an error of law**. *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996) (emphasis added).

IV. No Precedent Requires Patentability of Pre-critical Date Claims Under *§ 135(b)*

Carter maintains that pre-critical date claims must be patentable (Red Br. 37). Notably, Carter could not point to any legal precedent supporting its position that *§ 135(b)* requires pre-critical date claims to be patentable. Instead, Carter could only argue that the absence of observations in *Corbett* regarding the requirement of patentability of pre-critical date claims cannot be used as precedent that patentability of a pre-critical date claim is **not** a factor in a *§ 135(b)* determination (Red Br. 40-1, emphasis added). But Carter is wrong regarding the absence of observations in *Corbett* regarding the requirement of patentability of pre-critical date claims. In *Corbett*, four sets of pre-critical date claims (or 12 claims) were being analyzed to determine support for the post-critical date claim copied from the patent in interference. *Corbett*, 568 F.2d at 759-63. The court indicated that one claim (which made up one of the sets) was allowed. *Id.*, at 763. The court, thus, did make observations about the patentability of the pre-critical date claims, but clearly did not consider it a factor in its *§ 135(b)* analysis.

Carter's error regarding *Corbett* appears to be based upon a misreading of

the facts. Carter asserts that patentability was not an issue addressed by the court in *Corbett* because the pre-critical date claims and post-critical date claims were identical (Red Br. 40). Carter is wrong. One set of pre-critical date claims (four claims) was cancelled even before the involved patent had issued, so there clearly could not be any post-critical date claims identical to those claims. *Corbett* at 761.

Regardless, the fact that Carter could not point to any precedent in **support** of a requirement of showing patentability supports Adair's contention that such a requirement by the Board is legal error.

V. The Board Cannot Create Substantive Law

Adair maintains that the burden was upon Carter, as the movant, to show that **no** Adair pre-critical date claim supports the identity between the patent claim and the post-critical date claim. If the application claims priority to several applications and spans over 12 years of prosecution, as in the present case, the burden on the patentee can be quite onerous. No matter how onerous the patentee's burden may be, however, the Board does not get to shift the burden of persuasion to Adair through its creation of a presumption, particularly one as far-reaching as the one created here – i.e., that a cancelled pre-critical date claim is, *a priori*, materially different from the post-critical date claim. In support of the presumption created by the Board, Carter argues that courts routinely draw from related legal doctrines to support their decisions. The Board, however, is not a

court of law, and does not get to create substantive law. *See Merck & Co., Inc. v. Kessle*r, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) ("[T]he broadest of the PTO's rulemaking powers—35 U.S.C. §6(a)—authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [PTO]'; it does not grant the Commissioner the authority to issue substantive rules.")

VI. The Board Improperly Shifted The Burden Of Production To Adair

In addition to creating the presumption, the Board inappropriately shifted the burden of production to Adair. Citing 37 C.F.R. § 41.208(b), Carter contends that the USPTO's regulations only require a "**demonstration** that if unrebutted would justify the relief sought" by the movant to make out a *prima facie* showing (Red Br. 47, emphasis added). The cited rule does not require a mere demonstration, however, but rather a "showing." 37 C.F.R. § 41.208(b). As Adair stated previously, the burden was upon Carter to **show** that none of Adair's pre-critical date claims could be relied upon under *§ 135(b)* (Br. 17), not to **demonstrate** that some of Adair's pre-critical date claims could not be relied upon. Under Carter's analysis, demonstrating that **two** patent claims out of many are invalid would be sufficient to shift the burden of production to the patentee to show that **all** of its claims are valid. It is doubtful that Carter would argue that the burden should be shifted under such circumstances.

Carter further contends that the showing by Carter was completely reasonable in view of the page limitations for briefs in an interference. Carter alleges that it would have been impossible for Carter to separately address each of Adair's pre-critical date claims in the 25-page limit (Red Br. 48). Of course, Carter could have asked for a waiver of the page limit. Regardless, Adair is aware of no precedent excusing a party from meeting their burden because of a page limit.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Adair contends that the Board erred as a matter of law in finding that Adair claim 24 does 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: August 15, 2011

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CERTIFICATE OF SERVICE

United States Court of Appeals
for the Federal Circuit
No. **2011-1212 (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.
----------)

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 **15th Day of August, 2011**, I served the within **Reply Brief of Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage** upon:

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via Federal Express, overnight delivery by causing 2 true copies of each, enclosed in a properly addressed wrapper, to be deposited in an official depository of FedEx.

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

August 15, 2011

Elissa Matias

United States Court of Appeals for the Federal Circuit

(Interference No. 105,744)

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

v.

PAUL J. CARTER AND LEONARD G. PRESTA,
Appellees.

2011-1212

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

Decided: February 7, 2012

DOREEN YATKO TRUJILLO, Cozen O'Connor, P.C., of Philadelphia, Pennsylvania, argued for appellants. With her on the brief was KYLE VOS STRACHE.

OLIVER R. ASHE, JR., Ashe, P.C., of Reston, Virginia, argued for appellees. Of counsel on the brief were JEFFREY P. KUSHAN and RACHEL H. TOWNSEND, Sidley Austin, LLP, of Washington, DC.

Before RADER, *Chief Judge*, LINN and MOORE, *Circuit Judges*.

LINN, *Circuit Judge*.

Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage (collectively, "Adair") appeal a decision of the Board of Patent Appeals and Interferences ("Board") holding that Adair's single claim involved in Interference 105,744 with junior party Paul J. Carter and Leonard G. Presta (collectively, "Carter") was barred under 35 U.S.C. § 135(b)(1). Because the Board properly determined that Adair's claim was barred under § 135(b)(1), this court affirms.

I. BACKGROUND

On November 21, 2005, Adair filed U.S. Application Serial No. 11/284,261 ("'261 Application") with the United States Patent and Trademark Office ("PTO"). In a preliminary amendment filed concurrently with this application, Adair requested an interference based on Carter's U.S. Patent No. 6,407,213 ("'213 Patent"). The only count of the interference is drawn to humanized antibodies. More specifically, the count involves non-human amino acid substitutions on specific residues of the heavy chain variable domain (an antibody comprises two light chains and two heavy chains, each with a "constant" and "variable" domain). On February 2, 2010, the Board declared the interference, identifying the claims in the count to be claims 30, 31, 60, 62, 63, 66, 67, 70, 73, 77-81 of the '213 Patent and claim 24 of the '261 Application. *Carter v. Adair*, Interference No. 105,744, Declaration of Interference at 4 (Feb. 2, 2010). The Board awarded Adair priority benefit to PCT/GB90/02017 ("PCT Application"), filed December 21, 1990, which claims priority to a British application filed by Adair on December 21, 1989.

Claim 66 of Carter's '213 Patent, representative of the claims in the count and the basis for an interference-in-fact, recites:

> **66.** 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 [H=heavy], 73H, 76H, 78H, and 93H, utilizing the numbering system set forth in Kabat.

'213 Patent col.88 l.66-col.89 l.6.

Corresponding claim 24 in Adair's '261 Application recites:

> 24. 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.

'261 Application, Preliminary Amendment and Request for Interference dated Nov. 21, 2005 at 3, *as amended by* Amendment of Sept. 9, 2009 at 4 (added language emphasized).

Because Adair's claim 24 was not presented to the PTO prior to June 18, 2003, one year from issuance of the Carter '213 Patent (the "critical date") as required by 35 U.S.C. § 135(b)(1), Adair relied on pre-critical date claims

1 and 16 of the PCT Application and corresponding U.S. national stage Application No. 07/743,329 ("'329 Application") to avoid the bar of § 135(b)(1). Claims 1 and 16 recite:

> 1. 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.
>
> 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.

PCT Application at 67-69. Adair originally relied on claim 8 of the PCT Application, but because that claim related to light chains, Adair later abandoned that argument. In its request for rehearing before the Board, Adair argued for the first time that claim 2 of the PCT Application also provided pre-critical date support for claim 24, but the Board declined to consider this argument for the first time on rehearing. *Carter v. Adair*, Interference No. 105,774, Decision on Request for Rehearing at 4-5 (Nov. 5, 2010) ("*Rehearing*").

At the national stage, the examiner originally rejected each of Adair's PCT claims under one or more of the following sections: 101, 102(b), 103, and 112 first and second paragraphs. '329 Application, Office Action of November 18, 1992. Adair cancelled the PCT claims and added claims 23-66, later cancelled by an amendment adding claims 67-119 requiring multiple amino acid substitutions at specific locations in the heavy chain. '329

Application, Amendments of January 19, 1993 and April 16, 1993.

The Board rejected Adair's argument that claims 1 and 16 in the PCT Application provide pre-critical date support for claim 24 in the '261 Application because: (1) the PCT claims were not patentable to Adair; (2) Adair added limitations to overcome the examiner's rejection; and accordingly, (3) material differences presumptively existed between the post- and pre-critical date claims that Adair failed to rebut. *Carter v. Adair*, Interference No. 105,774, Decision on Motions at 9-10 (Aug. 30, 2010) ("*Decision*"). Citing *Regents of the University of California v. University of Iowa Research Foundation*, 455 F.3d 1371, 1377 (Fed. Cir. 2006), the Board stated that "[a]n 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." *Decision* at 10-11. On rehearing, the Board rejected Adair's assertion that materiality must be "determined in view of the patent claims being copied" and declined to compare Adair's post- or pre-critical date claims with copied claim 66 from Carter's '213 Patent. *Rehearing* at 3. Adair appeals, and this court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

A. Standard of Review

"We review the Board's construction of 35 U.S.C. § 135(b)(1) de novo, as statutory interpretation is a question of law." *In re Berger*, 279 F.3d 975, 980 (Fed. Cir. 2002).

B. Analysis

Adair argues that the Board erred by failing to assess material differences "in view of the patent claim being copied [claim 66 from Carter's '213 Patent]." Appellant Br. 22. According to Adair, this court's precedent does not endorse a test that allows the Board to completely ignore copied claim 66 from Carter's '213 Patent when assessing the material differences between the post- and pre-critical date claims. Adair argues that the materiality test from *Berger* and *Regents* requires an assessment of material limitations based on the "identity" between the post-critical date claim and copied claim 66 from Carter's '213 Patent—in other words, in view of the "count"—and not based on the post-critical date claim standing alone. *See Regents*, 455 F.3d at 1375 ("[A]s this court's precedent explains, California must demonstrate that claims in the '191 application provide pre-critical date support for the *post-critical date identity* between claim 205 [the post-critical date claim] and the '646 patent [the issued patent]." (emphasis added)); *Berger*, 279 F.3d at 983.

Carter counters that the question of "[w]hether there is a sufficient degree of identity between pre- and post-critical date claims for compliance with § 135(b) is an inquiry that is distinct and independent" from any comparison with the patent claims copied. Appellee Br. 33. According to Carter, the Board correctly interpreted § 135(b)(1) in holding that "establishing support for post-critical date claims does not entail looking at material limitations of the patented claims." *Id.* 42.

This court agrees with Carter. Section 135(b)(1) states:

> 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 appli-

> cation 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). Notwithstanding the seemingly strict language of the statute, a limited exception to this one year bar exists "where the copier had already been claiming substantially the same invention as the patentee" during the critical time period. *Corbett v. Chisholm*, 568 F.2d 759, 765 (CCPA 1977).

i.

In *Corbett*, the post-critical date claims "correspond[ed] exactly" with issued "Chisholm patent" claim 1. 568 F.2d at 759. The Board rejected Corbett's post-critical date claims under § 135(b)(1). *Id.* Corbett relied upon several groups of pre-critical date claims from the application and a predecessor application in an attempt to avoid the § 135(b) bar. *Id.* at 761-63. On appeal, this court compared the "copied claim" with the pre-critical date claims and affirmed the Board's finding that material differences precluded Corbett from relying on any of the pre-critical date claims to overcome the § 135(b) bar. *Id.* at 765-66. In identifying certain limitations of Chisholm patent claim 1 as "material," the court was simply noting the material differences that existed between that claim as copied by Corbett after the critical date and those pre-critical date claims Corbett was relying on to overcome the § 135(b) bar. The court did not establish any rule requiring some sort of threshold assessment of which limitations of the copied patent claim are material before determining whether material differences exist between post- and pre-critical date claims. In making this comparison, the court referenced Chisholm patent claim 1 only because that was the post-critical date claim.

Similarly, in *Berger*, the post-critical date claim was copied directly from and identical to issued "Muller patent" claim 1. 279 F.3d at 978. The examiner rejected Berger's pre-critical date claims 1-6 for indefiniteness and other grounds, and rejected post-critical date claim 7 under § 135(b)(1). *Id.* at 979. The Board rejected Berger's argument that claims 1-6 provided pre-critical date support for claim 7 because it found material differences between the "copied claim" and the pre-critical date claims, and this court affirmed. *Id.* at 982 ("The Board found the 'circumferential groove' limitation to be material because it was added by Muller during prosecution to avoid prior art. We agree with the Board's determination of materiality."). Again, the court in *Berger* referenced the issued Muller patent claim 1 only because the post-critical date claim, claim 7, was a direct copy of the patent claim. *Id.* at 981-83. This court affirmed the Board's analysis based only on the material differences between the *post- and pre-critical date claims*. *Id.* at 983 ("Because Berger's *original claims 1-6* [the pre-critical date claims] *do not include a material limitation of Berger claim 7* [the post-critical date claim], copied claim 7 is not entitled to the earlier effective date of those original claims for purposes of satisfying § 135(b)." (emphasis added)).

In *Regents*, this court expressly approved an analysis of material differences based solely on a comparison of the post- and pre-critical date claims in order to obtain the benefit of the earlier filing date:

> The Board compared claim 205 [the post-critical date claim] with claims 202-203 . . . and then with claim 204 [collectively, the pre-critical date claims]. The Board found that California's claim 205 contained material differences from claims 202-204. Therefore, claim 205 could not benefit from the earlier filing date of those claims. . . . On

> appeal, California does not contest the Board's finding of material differences between claim 205 and claims 202-204. Instead, California challenges the Board's conclusion that the correct inquiry under § 135(b)(1) asks whether claims 202-204 contain material differences from claim 205 and not whether claims 202-204 are to the same invention as claims in the '646 patent.

455 F.3d at 1373. The court in *Regents* rejected California's argument, explaining that "the relationship between the post- and pre-critical date claims . . . is not only relevant, but dispositive of the section 135(b)(1) question." *Id.* at 1374. Adair's arguments in this case are similar to California's arguments in *Regents*, where the court held that there is no requirement that the Board reference the issued patent claim(s) in the count to assess the material differences between the post- and pre-critical date claims. *Id.* at 1374-76.

The statement in *Regents* that the applicant's earlier filed claims must "provide pre-critical date support for the *post-critical date identity* between [the post-critical date claim] and the [issued patent]" to avoid the § 135(b)(1) bar, 455 F.3d at 1375 (emphasis added), does not require the Board to assess material differences in view of the issued patent claim(s) in the count. *See Berger*, 279 F.3d at 982. The question of material differences between post- and pre-critical date claims for purposes of overcoming a § 135(b) bar "is a distinctly different question from whether claims . . . are directed to the same or substantially the same subject matter" for purposes of provoking an interference. *Id.* As explained in *Regents*, § 135(b) is a statute of repose, intended to "limit[] the patentee's vulnerability to a declaration of an interference" by "limit[ing] the window of time in which the cause of the interference can occur." 455 F.3d at 1376. When a material difference exists between the post- and pre-critical

date claims, a belated interference is improper because it would be a "*different interference*[]" than that which "should have been earlier declared by the PTO." *Id.* (emphasis added).

For these reasons, this court holds that to overcome a § 135(b) bar for a post-critical date claim, an applicant must show that such claim is not materially different from a pre-critical date claim present in the application or any predecessor thereto in order to obtain the benefit of the earlier filing date. Any claims filed within the critical period, whether or not later cancelled, may provide pre-critical date support for the later filed patent claim(s), so long as the pre-critical date claims are not materially different from the later filed claim(s). *Corbett*, 568 F.2d at 765-66; *see also Regents*, 455 F.3d at 1373; *Berger*, 279 F.3d at 981-82.

Here, the Board found material differences between post-critical date claim 24 of the '261 Application and pre-critical date claims 1 and 16 of the PCT Application based on the prosecution history of the '261 Application. During prosecution, Adair added several limitations to claim 24—limitations not present in claims 1 and 16 of the PCT Application—to avoid examiner rejections during prosecution. *Decision* at 9. Adair failed to rebut the Board's finding with any evidence that the differences between claim 24 and claims 1 and 16 of the PCT Application were immaterial. *Id.* at 10. Adair criticizes the Board for failing to consider claim 66 from Carter's '213 Patent in assessing material differences. But, for the reasons explained above, an assessment of claim 66 was not necessary. What was required in determining whether the § 135(b) bar might be overcome was an assessment of the material differences between the post- and pre-critical date claims, which is precisely what the Board did.

ii.

Adair also contends that the Board erred in applying *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) in the context of an interference to conclude that a limitation added to a claim in response to a rejection that results in allowance is presumed to be necessary to patentability and therefore "material." Adair asserts that the burden of proof for the § 135(b) motion lay with Carter, and thus Adair cannot be faulted "for not providing any reason why the limitations that differ . . . were not material." Appellant Br. 25. Carter counters that "the Board's presumption of material differences is firmly grounded in the law." Appellee Br. 44. *See Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985); *Corbett*, 568 F.2d at 765.

Carter is correct. When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material. *See Festo*, 535 U.S. at 734; *Corbett*, 568 F.2d at 765. This presumption applies with equal force in the interference context. *Parks*, 773 F.2d at 1579 (holding in an interference case that "[t]he insertion of [a] limitation to overcome the examiner's rejection is *strong, if not conclusive, evidence of materiality*" (emphasis added)). Here, because Adair cancelled claims 1 and 16 of the PCT Application in response to the examiner's rejections, and added limitations into what eventually became claim 24 of the '261 Application to secure allowance, the Board properly presumed material differences between Adair's post- and pre-critical date claims. Adair failed to rebut this presumption.

iii.

Adair argues that the Board erred by establishing an absolute requirement that the pre-critical date claims be patentable to the applicant for the applicant to rely on those claims to avoid the § 135(b) bar. Carter counters that the Board did not articulate such a requirement, but even if it did, the requirement is appropriate. The Board quoted language from *Regents*, where this court stated that 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." *Regents*, 455 F.3d at 1377.

The court in *Regents* did not articulate a per se patentability requirement for an applicant to rely on pre-critical date claims, but rather observed that where material limitations are added to overcome an examiner's rejection after the critical date, there is "no inequity" in finding the later added claims barred under § 135(b)(1). Adair is correct that cancelled claims may be relied upon to avoid the § 135(b) bar. *See Corbett*, 568 F.2d at 765 ("The words 'prior to' in the present code clearly point to a 'critical date' prior to which . . . the copier had to be claiming the invention, whether or not the claims were subsequently cancelled."). Adair is incorrect, however, in contending that the Board established any absolute requirement that the pre-critical date claims must have been patentable to Adair. Even if it did, the error would have been harmless because the Board found material differences between the post- and pre-critical date claims, which Adair failed to rebut.

iv.

Finally, Adair argues that the Board abused its discretion in failing to consider claim 2 of the PCT Application as pre-critical date support for claim 24. The Board did not abuse its discretion in declining to consider claim 2 of the PCT Application for the first time on rehearing. 37 C.F.R. § 41.125(c), governing rehearing before the Board, provides that "[t]he burden of showing a decision should be modified lies with the party attacking the decision [and t]he request must specifically identify . . . (ii) The place *where the matter was previously addressed* in a motion, opposition, or reply." 37 C.F.R. § 41.125(c)(3) (emphasis added). Because Adair failed to previously address claim 2 prior to its petition for rehearing, the Board properly refused to consider it on rehearing.

III. CONCLUSION

For the foregoing reasons, this court affirms the decision of the Board.

AFFIRMED

2011-1212
(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,

Appellees.

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

PETITION FOR PANEL REHEARING of APPELLANTS JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL, and JOHN SPENCER EMTAGE

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Dated: March 7, 2012

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

March 7, 2012
Date

Doreen Yatko Trujillo
Signature of counsel

Doreen Yatko Trujillo
Printed name of counsel

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Blue Br. at ___	Appellant's Blue Brief at page ___
Gray Br. at___	Appellant's Gray Brief at page ___
Board	Board of Patent Appeals and Interferences

POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL

1. The panel's adoption of Carter's position that "establishing support for post-critical date claims does not entail looking at material limitations of the patented claims" misapprehends, and appears to directly conflict with, 35 U.S.C. § 135(b) and binding precedent of this Court.
2. The panel's assertion that the Board found that Adair added limitations to its post-critical date claim not present in its pre-critical date claims to avoid examiner rejections during prosecution is factually incorrect and not supported by the record.
3. The panel's requirement that Adair rebut a factual finding and a presumption before either was levied against Adair and, in the case of the presumption, before it was even created, is factually and legally impossible.
4. The panel's failure to address the differences between the two reported versions of *In re Berger* overlooks the fact that the two versions yield different results and, therefore, leaves a conflict unresolved.

ARGUMENT

In a precedential opinion, the panel affirmed the Board of Patent Appeals and Interferences ("Board") finding that Adair's claim involved in the interference, claim 24, was barred under 35 U.S.C. § 135(b). Slip Op. at 13. As indicated

above, and discussed in more detail below, the panel misapprehended or overlooked several points of law and fact in its opinion.

1. The panel's adoption of Carter's position that "establishing support for post-critical date claims does not entail looking at material limitations of the patented claims" misapprehends, and appears to directly conflict with, 35 U.S.C. § 135(b) and binding precedent of this Court.

Section 135(b) requires that a claim to, at least, substantially the same subject matter as **a claim of an issued patent** be made prior to one year from the date on which the patent was granted. 35 U.S.C. § 135(b) (emphasis added). As the panel noted "a limited exception to this one year bar statute exists 'where the copier had already been claiming substantially the same invention as the **patentee**' during the critical time period." Slip Op. at 7 (citing *Corbett v. Chisholm*, 568 F.2d 759, 765 (CCPA 1977)) (emphasis added). Section 135(b) does not require that the claim be identical to a claim of an issued patent, or that it be to the same subject matter as a claim of an issued patent, just that it be to substantially the same subject matter as a claim of an issued patent. A claim is to substantially the same subject matter as a claim of an issued patent if it has all material limitations of the patent claim, i.e., all limitations necessary to patentability of the patent claim. *Corbett* at 765-66.

Notwithstanding the foregoing, the panel adopted Carter's position that, to establish pre-critical date support for post-critical date claims, one does not need to consider the material limitations of the patented claims at all. Under the panel's

analysis, one only looks at the pre- and post-critical date claims of the provocateur of the interference. Under such an analysis, the pre-critical date claim could be lacking a material limitation of the patent claim, yet the interference could still proceed. Alternatively, as in the present case, the pre-critical date claims could contain all material limitations of the patent claim, which is all that § 135(b) requires, yet the interference will not proceed. The panel's adoption of the position that one does not need to consider the material limitations of the patent claims at all not only misapprehends § 135(b) and binding precedent of this Court, but it also appears to be in direct conflict with both.

In support of its position, the panel stated that the court in *Corbett* did not establish any rule requiring a threshold assessment of which limitations of the copied patent claim are material and "referenced Chisholm patent claim 1 only because that was the post-critical date claim." Slip. Op at 7. The panel's statement is not consistent with *Corbett*. The court in *Corbett* not only referred to the patented claim, but it also referred to Figures 1 and 4 of the patent to support its conclusion that the **patentee** contemplated sufficiently severe reduction and expansion steps. *Corbett* at 760. Both steps were considered to be material by the court in its assessment of compliance with § 135(b). *Id.*, at 765-6. Thus, the court in *Corbett* clearly made a threshold assessment of materiality based upon the patent claim. Notably, the court in *Corbett* did not argue that the limitations were

material simply because they were added by **Corbett**, the provocateur of the interference, to its own pre-critical date claims.

The panel made a similar assertion regarding *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002). The panel stated that the Court in *Berger* "referenced the issued Muller patent claim 1 only because the post-critical date claim, claim 7, was a direct copy of the patent claim." Slip Op. at 8 (citing *Berger* at 981-83). Again, the panel's statement is not consistent with *Berger*. The Court in *Berger* did not merely reference the patent claim; it referenced the prosecution history of the patent claim. The Court in *Berger* found that the limitation "circumferential groove" in the copied claim, i.e., the post-critical date claim, was material "because it was added by Muller [the patentee] during prosecution to avoid prior art." *Berger* at 982. The Court in *Berger* did not argue that the "circumferential groove" limitation was material because it was added by **Berger**, the provocateur of the interference, during prosecution of its own claims but, rather, because the limitation was added by **Muller**, the patentee, during prosecution of the patent claims.

To the extent the panel may take the position that the situation is different when the post-critical date claim is not identical to the patent claim, Adair directs the panel to *Parks v. Fine*, 773 F.2d 1577 (Fed. Cir. 1985). In *Parks*, the post-critical date claim was **not** identical to the patented claim. *Id.* at 1578. Once

again, however, the Court assessed materiality of a limitation based upon the patented claim. "The record establishes that the 'absence of a catalyst' limitation in the **Parks patent** claims and the contested counts is material. **Parks** inserted this limitation in his claims in response to, and to avoid, a rejection by the examiner." *Id.* at 1579 (emphasis added). The Court did not find that the limitation was material simply because it was added to the pre-critical date claims of **Fine**, the provocateur of the interference, but rather because it was added by **Parks**, the patentee, during prosecution of the patent claims.[1]

The only precedent arguably consistent with the panel's position is *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).[2] *Regents* is cited as approving an analysis of material differences based **solely** upon a comparison of post- and pre-critical date claims. Slip Op. at 8 (emphasis added). To the extent *Regents* approved such an analysis, however, it is not consistent with the prior binding precedent of this Court as discussed above, i.e., *Corbett*, *Berger*,

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[1] The panel relied upon *Parks* to support the levying of a presumption regarding materiality based upon Adair's prosecution, but seems to have overlooked the fact that the passage it relied upon was referring to what occurred during prosecution of the patent claim. Slip Op. at 11.

[2] *Regents* cites the correct standard for assessing compliance with § 135(b) -- "[A]s this court's **precedent** explains, California must demonstrate that claims in the '191 application provide pre-critical date support for the *post-critical date* ***identity*** between [the post-critical date claim] and the [issued patent]" -- but apparently did not apply it. *Id.* at 1375 (emphasis in bold added; emphasis in italics in Slip Op. at 9).

and *Parks*. Binding precedent cannot be overruled by a panel decision; binding precedent can only be overruled *en banc*. *Mothers Restaurant, Inc. v. Mama's Pizza, Inc.*, 723 F.2d 1566, 1573 (Fed. Cir. 1983).

2. The panel's assertion that the Board found that Adair added limitations to its post-critical date claim not present in its pre-critical date claims to avoid examiner rejections during prosecution is factually incorrect and not supported by the record.

Citing the Board's decision, the panel stated that one of the reasons the Board rejected Adair's arguments that claims 1 and 16 of the PCT Application provide pre-critical date support for claim 24 was because Adair added limitations to overcome the examiner's rejection. Slip. Op. at 5, 10. The Board, however, never stated that Adair had **added limitations** to claims 1 and 16, just that there were limitations that differed between involved claim 24 and claims 1 and 16:

> 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.

A10. Nor did the Board state what limitations allegedly differed between the two sets of claims; the Board simply levied a presumption of materiality based upon the cancellation of claims 1 and 16 after rejection. A9-10. Regardless, such a finding is not supported by the record. A comparison between claim 24 and claims 1 and 16 of the PCT Application reveals that **all** limitations of claim 24 are recited in

claims 1 and 16, including the two words emphasized by the panel. *See* Slip Op. at 3-4.

Further, the presumption of materiality levied by the Board, and approved by the panel, is based upon a fiction that the amendments to claim 24 on September 9, 2009 were in response to rejections levied almost 16 years earlier against different claims. A9-10; Slip Op. at 3, 11. The rejections being relied upon were levied November 18, 1992 against, among others, claims 1 and 16 of the PCT Application. A9. Claims 1 and 16 of the PCT Application were cancelled shortly thereafter, i.e., on January 19, 1993. A9. Claim 24 was added on November 21, 2005 to provoke the interference. Blue Br. at 4, 6. Claim 24 was clearly not amended on September 9, 2009 in response to a rejection levied almost 16 years earlier. By relying upon the presumption, the panel is disregarding the facts in favor of a fiction.

Indeed, it is difficult to understand how a presumption could ever be levied when, as a panel of this Court recently confirmed, multiple pre-critical date claims can be relied upon to show support for the post-critical date claim. *See Pioneer v. Monsanto,* No. 2011-1285, 2012 WL 612800 (Fed. Cir. February 28, 2012). If multiple claims can be relied upon to show support for post-critical date claims, then what happens to an individual claim, i.e., whether it was rejected or not, cannot be relevant. Consistent with this, *Pioneer* contained no analysis of what

happened to the pre-critical date claims during prosecution to arrive at the post-critical date claim, even though a review of the underlying facts reveals that the provocateur had admitted that at least one recitation in the post-critical date claim was added to overcome a rejection over the prior art. *Id.*[3]

3. The panel's requirement that Adair rebut a factual finding and a presumption before either was levied against Adair and, in the case of the presumption, before it was even created, is factually and legally impossible.

The panel criticized Adair for not rebutting the finding regarding pre-critical date claims 1 and 16 of the PCT Application with any evidence that the differences were immaterial. Slip Op. at 10. The panel made the same assertion regarding the presumption. Slip Op. at 11. First, the Board never identified which differences were material; instead the Board levied a presumption of materiality based on alleged differences. Second, both the finding and presumption were levied for the first time in the Board's decision. Indeed, the presumption was **created** for the

[3] Several differences between the post-critical date claim and the pre-critical date claims are evident in *Pioneer*, even when the pre-critical date claims are combined. In particular, the recitation "transformed cell" is completely absent from the pre-critical date claims. See *Pioneer*; Slip Op. at 7. Indeed, Monsanto, the provocateur of the interference, admitted that the "transformed cell" recitation was added to overcome an obviousness rejection. *Monsanto v. Pioneer,* Interference No. 105,728, Monsanto Opposition 1, Appendix 2 (March 25, 2010) (Material Facts 24 and 26-28 admitted by Monsanto); *Monsanto v. Pioneer,* Interference No. 105,728, Pioneer Motion 1, Appendix 2 (February 24, 2010). Yet, the Board did not even discuss materiality in its decision. *Monsanto v. Pioneer*, Interference 105,728, Decision, Bd. R. 125 (April 22, 2010). (All of the foregoing papers from Interference No. 105,728 are available on the United States Patent & Trademark Office's website, in the Interference Portal.)

first time in the Board's decision. Adair could not have rebutted either one before it was levied, which means that Adair could not have rebutted either one before it filed its request for rehearing.

The panel also asserted, however, that the Board did not abuse its discretion in refusing to consider a rebuttal argument Adair made in it its request for rehearing, i.e., that claim 2 of the PCT Application contained all material limitations of claim 24. Slip Op. at 13. The panel cited the rule governing rehearings before the Board that requires the requestor to show where it previously addressed a matter in a motion, opposition, or reply. *Id.* At the time Adair filed its opposition, however, no finding or presumption existed. Adair could not have addressed a finding or a presumption before it was levied. The panel has imposed a standard which is impossible for Adair to meet and has left Adair without any legal recourse. At a minimum, the panel should have considered claim 2 of the PCT Application, or remanded the matter to the Board to do so.

4. The panel's failure to address the differences between the two reported versions of *In re Berger* overlooks the fact that the two versions yield different results and, therefore, leaves a conflict unresolved.

As Adair pointed out in its reply brief, there is a discrepancy in the various reported versions of a statement in *Berger*. The Lexis® and Westlaw® electronic databases report the statement as follows:

> This is a distinctly different question from whether claims made for purposes of interference by different parties are directed to **interfering subject matter**.

Other electronic databases, as well as the book version of the Federal Reporter, report the statement as follows:

> This is a distinctly different question from whether claims made for purposes of interference by different parties are directed **to the same or substantially the same subject matter**.

Berger at 982. The differences between the two are highlighted in bold. *See* Gray Br. at 8. Without addressing the discrepancy, the panel relies upon the latter version to support its contention that material differences between post- and pre-critical date claims for purposes of overcoming a § 135(b) is a distinctly different question from whether the claims are directed to substantially the same subject matter. Slip Op. at 9. The Court should grant rehearing not only to clarify this conflict in the reported versions of *Berger*, but also because the outcome of the present appeal is clearly affected by which version is being relied upon -- the first version does not support the panel's contention.

Adair maintains that the correct version is the first one. As Adair argued previously, the sentence immediately preceding the statement in question sets forth what must be shown under § 135(b). Gray Br. at 8-9 and *Berger* at 981-82. As discussed above, § 135(b) recites the language "the same or substantially the same subject matter." 35 U.S.C. § 135(b). The sentence immediately following the

passage states that the "comparison standard of 37 C.F.R. § 1.601(n) was formulated not to determine the effective date of a claim in one party's application for compliance with § 135(b), but instead to define the extent of **interfering subject matter** as between applications of potentially conflicting parties." *Id.* at 982 (emphasis added). In the statement in question, then, interfering subject matter under (prior) 37 C.F.R. § 1.601(n) was being distinguished from the requirements under § 135(b), which is consistent with the first reported version. *Id* at 981-82. Further, under the second reported version, showing that claims are to the *same or substantially the same subject matter* is being distinguished from showing that claims are to the *same or substantially the same subject matter,* which is a distinction without a difference.

CONCLUSION

The petition for panel rehearing should be granted.

Respectfully Submitted,

Dated: March 7, 2012

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ADDENDUM

United States Court of Appeals for the Federal Circuit

(Interference No. 105,744)

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

v.

PAUL J. CARTER AND LEONARD G. PRESTA,
Appellees.

2011-1212

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

Decided: February 7, 2012

DOREEN YATKO TRUJILLO, Cozen O'Connor, P.C., of Philadelphia, Pennsylvania, argued for appellants. With her on the brief was KYLE VOS STRACHE.

OLIVER R. ASHE, JR., Ashe, P.C., of Reston, Virginia, argued for appellees. Of counsel on the brief were JEFFREY P. KUSHAN and RACHEL H. TOWNSEND, Sidley Austin, LLP, of Washington, DC.

Before RADER, *Chief Judge*, LINN and MOORE, *Circuit Judges*.

LINN, *Circuit Judge*.

Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage (collectively, "Adair") appeal a decision of the Board of Patent Appeals and Interferences ("Board") holding that Adair's single claim involved in Interference 105,744 with junior party Paul J. Carter and Leonard G. Presta (collectively, "Carter") was barred under 35 U.S.C. § 135(b)(1). Because the Board properly determined that Adair's claim was barred under § 135(b)(1), this court affirms.

I. BACKGROUND

On November 21, 2005, Adair filed U.S. Application Serial No. 11/284,261 ("'261 Application") with the United States Patent and Trademark Office ("PTO"). In a preliminary amendment filed concurrently with this application, Adair requested an interference based on Carter's U.S. Patent No. 6,407,213 ("'213 Patent"). The only count of the interference is drawn to humanized antibodies. More specifically, the count involves non-human amino acid substitutions on specific residues of the heavy chain variable domain (an antibody comprises two light chains and two heavy chains, each with a "constant" and "variable" domain). On February 2, 2010, the Board declared the interference, identifying the claims in the count to be claims 30, 31, 60, 62, 63, 66, 67, 70, 73, 77-81 of the '213 Patent and claim 24 of the '261 Application. *Carter v. Adair*, Interference No. 105,744, Declaration of Interference at 4 (Feb. 2, 2010). The Board awarded Adair priority benefit to PCT/GB90/02017 ("PCT Application"), filed December 21, 1990, which claims priority to a British application filed by Adair on December 21, 1989.

Claim 66 of Carter's '213 Patent, representative of the claims in the count and the basis for an interference-in-fact, recites:

> **66.** 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 [H=heavy], 73H, 76H, 78H, and 93H, utilizing the numbering system set forth in Kabat.

'213 Patent col.88 l.66-col.89 l.6.

Corresponding claim 24 in Adair's '261 Application recites:

> **24.** 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.

'261 Application, Preliminary Amendment and Request for Interference dated Nov. 21, 2005 at 3, *as amended by* Amendment of Sept. 9, 2009 at 4 (added language emphasized).

Because Adair's claim 24 was not presented to the PTO prior to June 18, 2003, one year from issuance of the Carter '213 Patent (the "critical date") as required by 35 U.S.C. § 135(b)(1), Adair relied on pre-critical date claims

1 and 16 of the PCT Application and corresponding U.S. national stage Application No. 07/743,329 ("'329 Application") to avoid the bar of § 135(b)(1). Claims 1 and 16 recite:

> 1. 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.
>
> 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.

PCT Application at 67-69. Adair originally relied on claim 8 of the PCT Application, but because that claim related to light chains, Adair later abandoned that argument. In its request for rehearing before the Board, Adair argued for the first time that claim 2 of the PCT Application also provided pre-critical date support for claim 24, but the Board declined to consider this argument for the first time on rehearing. *Carter v. Adair*, Interference No. 105,774, Decision on Request for Rehearing at 4-5 (Nov. 5, 2010) ("*Rehearing*").

At the national stage, the examiner originally rejected each of Adair's PCT claims under one or more of the following sections: 101, 102(b), 103, and 112 first and second paragraphs. '329 Application, Office Action of November 18, 1992. Adair cancelled the PCT claims and added claims 23-66, later cancelled by an amendment adding claims 67-119 requiring multiple amino acid substitutions at specific locations in the heavy chain. '329

Application, Amendments of January 19, 1993 and April 16, 1993.

The Board rejected Adair's argument that claims 1 and 16 in the PCT Application provide pre-critical date support for claim 24 in the '261 Application because: (1) the PCT claims were not patentable to Adair; (2) Adair added limitations to overcome the examiner's rejection; and accordingly, (3) material differences presumptively existed between the post- and pre-critical date claims that Adair failed to rebut. *Carter v. Adair*, Interference No. 105,774, Decision on Motions at 9-10 (Aug. 30, 2010) ("*Decision*"). Citing *Regents of the University of California v. University of Iowa Research Foundation*, 455 F.3d 1371, 1377 (Fed. Cir. 2006), the Board stated that "[a]n 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." *Decision* at 10-11. On rehearing, the Board rejected Adair's assertion that materiality must be "determined in view of the patent claims being copied" and declined to compare Adair's post- or pre-critical date claims with copied claim 66 from Carter's '213 Patent. *Rehearing* at 3. Adair appeals, and this court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

A. Standard of Review

"We review the Board's construction of 35 U.S.C. § 135(b)(1) de novo, as statutory interpretation is a question of law." *In re Berger*, 279 F.3d 975, 980 (Fed. Cir. 2002).

B. Analysis

Adair argues that the Board erred by failing to assess material differences "in view of the patent claim being copied [claim 66 from Carter's '213 Patent]." Appellant Br. 22. According to Adair, this court's precedent does not endorse a test that allows the Board to completely ignore copied claim 66 from Carter's '213 Patent when assessing the material differences between the post- and pre-critical date claims. Adair argues that the materiality test from *Berger* and *Regents* requires an assessment of material limitations based on the "identity" between the post-critical date claim and copied claim 66 from Carter's '213 Patent—in other words, in view of the "count"—and not based on the post-critical date claim standing alone. *See Regents*, 455 F.3d at 1375 ("[A]s this court's precedent explains, California must demonstrate that claims in the '191 application provide pre-critical date support for the *post-critical date identity* between claim 205 [the post-critical date claim] and the '646 patent [the issued patent]." (emphasis added)); *Berger*, 279 F.3d at 983.

Carter counters that the question of "[w]hether there is a sufficient degree of identity between pre- and post-critical date claims for compliance with § 135(b) is an inquiry that is distinct and independent" from any comparison with the patent claims copied. Appellee Br. 33. According to Carter, the Board correctly interpreted § 135(b)(1) in holding that "establishing support for post-critical date claims does not entail looking at material limitations of the patented claims." *Id.* 42.

This court agrees with Carter. Section 135(b)(1) states:

> 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 appli-

> cation 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). Notwithstanding the seemingly strict language of the statute, a limited exception to this one year bar exists "where the copier had already been claiming substantially the same invention as the patentee" during the critical time period. *Corbett v. Chisholm*, 568 F.2d 759, 765 (CCPA 1977).

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In *Corbett*, the post-critical date claims "correspond[ed] exactly" with issued "Chisholm patent" claim 1. 568 F.2d at 759. The Board rejected Corbett's post-critical date claims under § 135(b)(1). *Id.* Corbett relied upon several groups of pre-critical date claims from the application and a predecessor application in an attempt to avoid the § 135(b) bar. *Id.* at 761-63. On appeal, this court compared the "copied claim" with the pre-critical date claims and affirmed the Board's finding that material differences precluded Corbett from relying on any of the pre-critical date claims to overcome the § 135(b) bar. *Id.* at 765-66. In identifying certain limitations of Chisholm patent claim 1 as "material," the court was simply noting the material differences that existed between that claim as copied by Corbett after the critical date and those pre-critical date claims Corbett was relying on to overcome the § 135(b) bar. The court did not establish any rule requiring some sort of threshold assessment of which limitations of the copied patent claim are material before determining whether material differences exist between post- and pre-critical date claims. In making this comparison, the court referenced Chisholm patent claim 1 only because that was the post-critical date claim.

Similarly, in *Berger*, the post-critical date claim was copied directly from and identical to issued "Muller patent" claim 1. 279 F.3d at 978. The examiner rejected Berger's pre-critical date claims 1-6 for indefiniteness and other grounds, and rejected post-critical date claim 7 under § 135(b)(1). *Id.* at 979. The Board rejected Berger's argument that claims 1-6 provided pre-critical date support for claim 7 because it found material differences between the "copied claim" and the pre-critical date claims, and this court affirmed. *Id.* at 982 ("The Board found the 'circumferential groove' limitation to be material because it was added by Muller during prosecution to avoid prior art. We agree with the Board's determination of materiality."). Again, the court in *Berger* referenced the issued Muller patent claim 1 only because the post-critical date claim, claim 7, was a direct copy of the patent claim. *Id.* at 981-83. This court affirmed the Board's analysis based only on the material differences between the *post- and pre-critical date claims*. *Id.* at 983 ("Because Berger's *original claims 1-6* [the pre-critical date claims] *do not include a material limitation of Berger claim 7* [the post-critical date claim], copied claim 7 is not entitled to the earlier effective date of those original claims for purposes of satisfying § 135(b)." (emphasis added)).

In *Regents*, this court expressly approved an analysis of material differences based solely on a comparison of the post- and pre-critical date claims in order to obtain the benefit of the earlier filing date:

> The Board compared claim 205 [the post-critical date claim] with claims 202-203 . . . and then with claim 204 [collectively, the pre-critical date claims]. The Board found that California's claim 205 contained material differences from claims 202-204. Therefore, claim 205 could not benefit from the earlier filing date of those claims. . . . On

> appeal, California does not contest the Board's finding of material differences between claim 205 and claims 202-204. Instead, California challenges the Board's conclusion that the correct inquiry under § 135(b)(1) asks whether claims 202-204 contain material differences from claim 205 and not whether claims 202-204 are to the same invention as claims in the '646 patent.

455 F.3d at 1373. The court in *Regents* rejected California's argument, explaining that "the relationship between the post- and pre-critical date claims . . . is not only relevant, but dispositive of the section 135(b)(1) question." *Id.* at 1374. Adair's arguments in this case are similar to California's arguments in *Regents*, where the court held that there is no requirement that the Board reference the issued patent claim(s) in the count to assess the material differences between the post- and pre-critical date claims. *Id.* at 1374-76.

The statement in *Regents* that the applicant's earlier filed claims must "provide pre-critical date support for the *post-critical date identity* between [the post-critical date claim] and the [issued patent]" to avoid the § 135(b)(1) bar, 455 F.3d at 1375 (emphasis added), does not require the Board to assess material differences in view of the issued patent claim(s) in the count. *See Berger*, 279 F.3d at 982. The question of material differences between post- and pre-critical date claims for purposes of overcoming a § 135(b) bar "is a distinctly different question from whether claims . . . are directed to the same or substantially the same subject matter" for purposes of provoking an interference. *Id.* As explained in *Regents*, § 135(b) is a statute of repose, intended to "limit[] the patentee's vulnerability to a declaration of an interference" by "limit[ing] the window of time in which the cause of the interference can occur." 455 F.3d at 1376. When a material difference exists between the post- and pre-critical

date claims, a belated interference is improper because it would be a "*different interference*[]" than that which "should have been earlier declared by the PTO." *Id.* (emphasis added).

For these reasons, this court holds that to overcome a § 135(b) bar for a post-critical date claim, an applicant must show that such claim is not materially different from a pre-critical date claim present in the application or any predecessor thereto in order to obtain the benefit of the earlier filing date. Any claims filed within the critical period, whether or not later cancelled, may provide pre-critical date support for the later filed patent claim(s), so long as the pre-critical date claims are not materially different from the later filed claim(s). *Corbett*, 568 F.2d at 765-66; *see also Regents*, 455 F.3d at 1373; *Berger*, 279 F.3d at 981-82.

Here, the Board found material differences between post-critical date claim 24 of the '261 Application and pre-critical date claims 1 and 16 of the PCT Application based on the prosecution history of the '261 Application. During prosecution, Adair added several limitations to claim 24—limitations not present in claims 1 and 16 of the PCT Application—to avoid examiner rejections during prosecution. *Decision* at 9. Adair failed to rebut the Board's finding with any evidence that the differences between claim 24 and claims 1 and 16 of the PCT Application were immaterial. *Id.* at 10. Adair criticizes the Board for failing to consider claim 66 from Carter's '213 Patent in assessing material differences. But, for the reasons explained above, an assessment of claim 66 was not necessary. What was required in determining whether the § 135(b) bar might be overcome was an assessment of the material differences between the post- and pre-critical date claims, which is precisely what the Board did.

ii.

Adair also contends that the Board erred in applying *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) in the context of an interference to conclude that a limitation added to a claim in response to a rejection that results in allowance is presumed to be necessary to patentability and therefore "material." Adair asserts that the burden of proof for the § 135(b) motion lay with Carter, and thus Adair cannot be faulted "for not providing any reason why the limitations that differ . . . were not material." Appellant Br. 25. Carter counters that "the Board's presumption of material differences is firmly grounded in the law." Appellee Br. 44. *See Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985); *Corbett*, 568 F.2d at 765.

Carter is correct. When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material. *See Festo*, 535 U.S. at 734; *Corbett*, 568 F.2d at 765. This presumption applies with equal force in the interference context. *Parks*, 773 F.2d at 1579 (holding in an interference case that "[t]he insertion of [a] limitation to overcome the examiner's rejection is *strong, if not conclusive, evidence of materiality*" (emphasis added)). Here, because Adair cancelled claims 1 and 16 of the PCT Application in response to the examiner's rejections, and added limitations into what eventually became claim 24 of the '261 Application to secure allowance, the Board properly presumed material differences between Adair's post- and pre-critical date claims. Adair failed to rebut this presumption.

iii.

Adair argues that the Board erred by establishing an absolute requirement that the pre-critical date claims be patentable to the applicant for the applicant to rely on those claims to avoid the § 135(b) bar. Carter counters that the Board did not articulate such a requirement, but even if it did, the requirement is appropriate. The Board quoted language from *Regents*, where this court stated that 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." *Regents*, 455 F.3d at 1377.

The court in *Regents* did not articulate a per se patentability requirement for an applicant to rely on pre-critical date claims, but rather observed that where material limitations are added to overcome an examiner's rejection after the critical date, there is "no inequity" in finding the later added claims barred under § 135(b)(1). Adair is correct that cancelled claims may be relied upon to avoid the § 135(b) bar. *See Corbett*, 568 F.2d at 765 ("The words 'prior to' in the present code clearly point to a 'critical date' prior to which . . . the copier had to be claiming the invention, whether or not the claims were subsequently cancelled."). Adair is incorrect, however, in contending that the Board established any absolute requirement that the pre-critical date claims must have been patentable to Adair. Even if it did, the error would have been harmless because the Board found material differences between the post- and pre-critical date claims, which Adair failed to rebut.

iv.

Finally, Adair argues that the Board abused its discretion in failing to consider claim 2 of the PCT Application as pre-critical date support for claim 24. The Board did not abuse its discretion in declining to consider claim 2 of the PCT Application for the first time on rehearing. 37 C.F.R. § 41.125(c), governing rehearing before the Board, provides that "[t]he burden of showing a decision should be modified lies with the party attacking the decision [and t]he request must specifically identify . . . (ii) The place *where the matter was previously addressed* in a motion, opposition, or reply." 37 C.F.R. § 41.125(c)(3) (emphasis added). Because Adair failed to previously address claim 2 prior to its petition for rehearing, the Board properly refused to consider it on rehearing.

III. CONCLUSION

For the foregoing reasons, this court affirms the decision of the Board.

AFFIRMED

CERTIFICATE OF SERVICE

United States Court of Appeals
for the Federal Circuit
No. **2011-1212 (Interference No. 105,744)**
----------)
John Robert Adair, Diljeet Singh Athwal, and
John Spencer Emtage

Appellants,

v.

Paul J. Carter and Leonard G. Presta,

Appellees.
----------)

I, Robyn Cocho, 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.

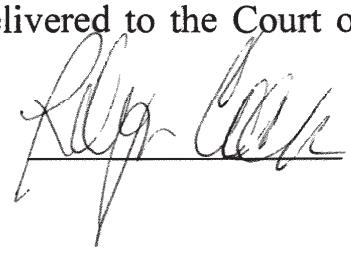
On the **7th Day of March, 2012**, I served the within **Petition for Panel Rehearing of Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage** upon:

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, overnight delivery by causing 2 true copies of each, enclosed in a properly addressed wrapper, to be deposited in an official depository of FedEx.

Unless otherwise noted, 19 copies have been delivered to the Court on the same date via Federal Express

March 7, 2012



United States Court of Appeals for the Federal Circuit

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Appellees.

Judgment

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

in CASE NO(S). Interference No. 105,744

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

DATED FEB – 7 2012

Jan Horbaly, Clerk

CERTIFIED COPY
I HEREBY CERTIFY THIS DOCUMENT
IS A TRUE AND CORRECT COPY
OF THE ORIGINAL ON FILE.
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ISSUED AS A MANDATE: APR – 2 2012

United States Court of Appeals for the Federal Circuit

(Interference No. 105,744)

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Appellants,

v.

PAUL J. CARTER AND LEONARD G. PRESTA,
Appellees.

2011-1212

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

Decided: February 7, 2012

DOREEN YATKO TRUJILLO, Cozen O'Connor, P.C., of Philadelphia, Pennsylvania, argued for appellants. With her on the brief was KYLE VOS STRACHE.

OLIVER R. ASHE, JR., Ashe, P.C., of Reston, Virginia, argued for appellees. Of counsel on the brief were JEFFREY P. KUSHAN and RACHEL H. TOWNSEND, Sidley Austin, LLP, of Washington, DC.

Before RADER, *Chief Judge*, LINN and MOORE, *Circuit Judges*.

LINN, *Circuit Judge*.

Appellants John Robert Adair, Diljeet Singh Athwal, and John Spencer Emtage (collectively, "Adair") appeal a decision of the Board of Patent Appeals and Interferences ("Board") holding that Adair's single claim involved in Interference 105,744 with junior party Paul J. Carter and Leonard G. Presta (collectively, "Carter") was barred under 35 U.S.C. § 135(b)(1). Because the Board properly determined that Adair's claim was barred under § 135(b)(1), this court affirms.

I. BACKGROUND

On November 21, 2005, Adair filed U.S. Application Serial No. 11/284,261 ("'261 Application") with the United States Patent and Trademark Office ("PTO"). In a preliminary amendment filed concurrently with this application, Adair requested an interference based on Carter's U.S. Patent No. 6,407,213 ("'213 Patent"). The only count of the interference is drawn to humanized antibodies. More specifically, the count involves non-human amino acid substitutions on specific residues of the heavy chain variable domain (an antibody comprises two light chains and two heavy chains, each with a "constant" and "variable" domain). On February 2, 2010, the Board declared the interference, identifying the claims in the count to be claims 30, 31, 60, 62, 63, 66, 67, 70, 73, 77-81 of the '213 Patent and claim 24 of the '261 Application. *Carter v. Adair*, Interference No. 105,744, Declaration of Interference at 4 (Feb. 2, 2010). The Board awarded Adair priority benefit to PCT/GB90/02017 ("PCT Application"), filed December 21, 1990, which claims priority to a British application filed by Adair on December 21, 1989.

Claim 66 of Carter's '213 Patent, representative of the claims in the count and the basis for an interference-in-fact, recites:

> **66.** 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 [H=heavy], 73H, 76H, 78H, and 93H, utilizing the numbering system set forth in Kabat.

'213 Patent col.88 l.66-col.89 l.6.

Corresponding claim 24 in Adair's '261 Application recites:

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'261 Application, Preliminary Amendment and Request for Interference dated Nov. 21, 2005 at 3, *as amended by* Amendment of Sept. 9, 2009 at 4 (added language emphasized).

Because Adair's claim 24 was not presented to the PTO prior to June 18, 2003, one year from issuance of the Carter '213 Patent (the "critical date") as required by 35 U.S.C. § 135(b)(1), Adair relied on pre-critical date claims

1 and 16 of the PCT Application and corresponding U.S. national stage Application No. 07/743,329 ("'329 Application") to avoid the bar of § 135(b)(1). Claims 1 and 16 recite:

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This court agrees with Carter. Section 135(b)(1) states:

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> The Board compared claim 205 [the post-critical date claim] with claims 202-203 . . . and then with claim 204 [collectively, the pre-critical date claims]. The Board found that California's claim 205 contained material differences from claims 202-204. Therefore, claim 205 could not benefit from the earlier filing date of those claims. . . . On

> appeal, California does not contest the Board's finding of material differences between claim 205 and claims 202-204. Instead, California challenges the Board's conclusion that the correct inquiry under § 135(b)(1) asks whether claims 202-204 contain material differences from claim 205 and not whether claims 202-204 are to the same invention as claims in the '646 patent.

455 F.3d at 1373. The court in *Regents* rejected California's argument, explaining that "the relationship between the post- and pre-critical date claims . . . is not only relevant, but dispositive of the section 135(b)(1) question." *Id.* at 1374. Adair's arguments in this case are similar to California's arguments in *Regents*, where the court held that there is no requirement that the Board reference the issued patent claim(s) in the count to assess the material differences between the post- and pre-critical date claims. *Id.* at 1374-76.

The statement in *Regents* that the applicant's earlier filed claims must "provide pre-critical date support for the *post-critical date identity* between [the post-critical date claim] and the [issued patent]" to avoid the § 135(b)(1) bar, 455 F.3d at 1375 (emphasis added), does not require the Board to assess material differences in view of the issued patent claim(s) in the count. *See Berger*, 279 F.3d at 982. The question of material differences between post- and pre-critical date claims for purposes of overcoming a § 135(b) bar "is a distinctly different question from whether claims . . . are directed to the same or substantially the same subject matter" for purposes of provoking an interference. *Id.* As explained in *Regents*, § 135(b) is a statute of repose, intended to "limit[] the patentee's vulnerability to a declaration of an interference" by "limit[ing] the window of time in which the cause of the interference can occur." 455 F.3d at 1376. When a material difference exists between the post- and pre-critical

date claims, a belated interference is improper because it would be a "*different interference*[]" than that which "should have been earlier declared by the PTO." *Id.* (emphasis added).

For these reasons, this court holds that to overcome a § 135(b) bar for a post-critical date claim, an applicant must show that such claim is not materially different from a pre-critical date claim present in the application or any predecessor thereto in order to obtain the benefit of the earlier filing date. Any claims filed within the critical period, whether or not later cancelled, may provide pre-critical date support for the later filed patent claim(s), so long as the pre-critical date claims are not materially different from the later filed claim(s). *Corbett*, 568 F.2d at 765-66; *see also Regents*, 455 F.3d at 1373; *Berger*, 279 F.3d at 981-82.

Here, the Board found material differences between post-critical date claim 24 of the '261 Application and pre-critical date claims 1 and 16 of the PCT Application based on the prosecution history of the '261 Application. During prosecution, Adair added several limitations to claim 24—limitations not present in claims 1 and 16 of the PCT Application—to avoid examiner rejections during prosecution. *Decision* at 9. Adair failed to rebut the Board's finding with any evidence that the differences between claim 24 and claims 1 and 16 of the PCT Application were immaterial. *Id.* at 10. Adair criticizes the Board for failing to consider claim 66 from Carter's '213 Patent in assessing material differences. But, for the reasons explained above, an assessment of claim 66 was not necessary. What was required in determining whether the § 135(b) bar might be overcome was an assessment of the material differences between the post- and pre-critical date claims, which is precisely what the Board did.

ii.

Adair also contends that the Board erred in applying *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) in the context of an interference to conclude that a limitation added to a claim in response to a rejection that results in allowance is presumed to be necessary to patentability and therefore "material." Adair asserts that the burden of proof for the § 135(b) motion lay with Carter, and thus Adair cannot be faulted "for not providing any reason why the limitations that differ . . . were not material." Appellant Br. 25. Carter counters that "the Board's presumption of material differences is firmly grounded in the law." Appellee Br. 44. *See Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985); *Corbett*, 568 F.2d at 765.

Carter is correct. When an applicant adds limitations in response to an examiner's rejection, and those limitations result in allowance, there exists a well established presumption that those limitations are necessary to patentability and thus material. *See Festo*, 535 U.S. at 734; *Corbett*, 568 F.2d at 765. This presumption applies with equal force in the interference context. *Parks*, 773 F.2d at 1579 (holding in an interference case that "[t]he insertion of [a] limitation to overcome the examiner's rejection is *strong, if not conclusive, evidence of materiality*" (emphasis added)). Here, because Adair cancelled claims 1 and 16 of the PCT Application in response to the examiner's rejections, and added limitations into what eventually became claim 24 of the '261 Application to secure allowance, the Board properly presumed material differences between Adair's post- and pre-critical date claims. Adair failed to rebut this presumption.

iii.

Adair argues that the Board erred by establishing an absolute requirement that the pre-critical date claims be patentable to the applicant for the applicant to rely on those claims to avoid the § 135(b) bar. Carter counters that the Board did not articulate such a requirement, but even if it did, the requirement is appropriate. The Board quoted language from *Regents*, where this court stated that 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." *Regents*, 455 F.3d at 1377.

The court in *Regents* did not articulate a per se patentability requirement for an applicant to rely on pre-critical date claims, but rather observed that where material limitations are added to overcome an examiner's rejection after the critical date, there is "no inequity" in finding the later added claims barred under § 135(b)(1). Adair is correct that cancelled claims may be relied upon to avoid the § 135(b) bar. *See Corbett*, 568 F.2d at 765 ("The words 'prior to' in the present code clearly point to a 'critical date' prior to which . . . the copier had to be claiming the invention, whether or not the claims were subsequently cancelled."). Adair is incorrect, however, in contending that the Board established any absolute requirement that the pre-critical date claims must have been patentable to Adair. Even if it did, the error would have been harmless because the Board found material differences between the post- and pre-critical date claims, which Adair failed to rebut.

iv.

Finally, Adair argues that the Board abused its discretion in failing to consider claim 2 of the PCT Application as pre-critical date support for claim 24. The Board did not abuse its discretion in declining to consider claim 2 of the PCT Application for the first time on rehearing. 37 C.F.R. § 41.125(c), governing rehearing before the Board, provides that "[t]he burden of showing a decision should be modified lies with the party attacking the decision [and t]he request must specifically identify . . . (ii) The place *where the matter was previously addressed* in a motion, opposition, or reply." 37 C.F.R. § 41.125(c)(3) (emphasis added). Because Adair failed to previously address claim 2 prior to its petition for rehearing, the Board properly refused to consider it on rehearing.

III. CONCLUSION

For the foregoing reasons, this court affirms the decision of the Board.

AFFIRMED