UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CYTOLOGIC, INC., and COLORADO STATE UNIVERSITY RESEARCH FOUNDATION, Plaintiffs, v. BIOPHERESIS GMBH, and BIOPHERESIS TECHNOLOGIES, INC., Defendants.	Civil Action No. 08-978 (CKK)

MEMORANDUM OPINION
(January 15, 2010)

Plaintiffs, Cytologic, Inc. and Colorado State University Research Foundation (collectively, "Cytologic"), filed the above-captioned action challenging the actions and decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office pursuant to 35 U.S.C. § 146. Cytologic named as Defendants Biopheresis GMBH, and Biopheresis Technologies, Inc. (collectively, "Biopheresis"). Presently before the Court is Cytologic's [20] Motion for Summary Judgment to Vacate Interference Pursuant to 35 U.S.C. § 135(b)(1) and Request for Oral Hearing. After a searching review of the parties' briefing, the administrative record, the relevant case law, and the entire record herein, the Court shall DENY Cytologic's [20] Motion for Summary Judgment to Vacate Interference Pursuant to 35 U.S.C. §

135(b)(1) and Request for Oral Hearing, for the reasons set forth below. Specifically, the Court finds that the Board of Patent Appeals and Interferences (the "Board") correctly allocated the burden of proof with respect to Cytologic's preliminary Section 135(b)(1) Motion and that Cytologic is precluded from raising new arguments regarding materiality before this Court that were not presented to the Board below.

I. BACKGROUND

As is explained in more detail below, Cytologic's now-pending motion for summary judgment is narrow in focus and raises only two discrete challenges to the Board's decision below. Consequently, much of the proceedings before the Board are not directly relevant to the instant Memorandum Opinion. Indeed, given the Court's ultimate resolution of Cytologic's motion, the Court does not herein reach the substantive merits of any of the Board's findings of fact in the interference proceedings. Nonetheless, in order to better understand Cytologic's pending motion and the arguments raised therein, it is necessary to provide a brief review of the relevant patent and interference law as well as the general factual background of this case so that Cytologic's current arguments may be placed in the proper context.

A. Patent and Interference Background

1. Patent Prosecution

The process of obtaining a patent is known as "prosecution"and begins with the filing of an application with the Patent and Trademark Office ("PTO"). *See Intervet, Inc. v. Merial Ltd.*, 643 F. Supp. 2d 97, 99 (D.D.C. 2009); *see generally* 37 C.F.R. § 1.51. A patent application consists of a specification of the proposed patent, including a claim or claims, an oath or declaration, drawings as may be necessary, and the appropriate filing fee. 37 C.F.R. § 1.51(b).

Focusing on the specification in particular, as Judge Henry H. Kennedy, Jr. aptly explained in a recent decision,

> [a] specification must include both a written description of the invention and an enablement for a claimed invention that explains the "manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." At the end of the written description and enablement, a proper specification should conclude with a list of "claims," which identify the specific innovations, components or subparts of the invention, the applicant regards as hers. A claim is a single sentence description of what the applicant believes to be her invention, setting the boundaries of the invention the applicant wishes the PTO to examine. A single claim can be composed of multiple elements and/or limitations.[1] Elements are the previously known physical components that make up the claimed invention. Limitations, on the other hand, usually describe the claim's restrictions. An application may contain several claims, and each claim usually contains several restrictions. It is these claims that define the scope of patent protection.

Intervet, 643 F. Supp. 2d at 99 (internal citations omitted).

A patent examiner then reviews the application to determine whether a patent should issue. "On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention." 37 C.F.R. § 1.104(a)(1). If the patent examiner determines that the applicant is entitled to a patent under the law, a "Notice of Allowance" is issued. *Id.* § 1.311(a). If, however, the patent examiner determines that there are deficiencies or problems with the application, the examiner will issue an "Office Action" advising the applicant as to the "reasons for any adverse action or any objection or requirement." *Id.* § 1.104(a)(2). Upon receipt of an Office Action, an applicant may

[1] A claim may be either independent or dependent. An independent claim stands alone and does not refer to another claim, while a dependent claim makes express reference to one or more previous claims and includes all of the limitations of the earlier claims, as well as the new limitation(s) found only in the dependent claim. *See* 35 U.S.C. § 112.

amend the claims, argue as to the merits of the examiner's findings, or both. *See id.* § 1.111. This back and forth between the applicant and the patent examiner continues until a patent is issued or a final rejection occurs.

2. Patent Interference Practice

United States patent law, unlike much of the rest of the world, is premised on the principle that the first to invent — rather than the first to file a patent application — is granted the patent right. ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT, 1151 (2009). As a consequence of this rule, there must be a mechanism for determining who among multiple patent applicants, or, as in this case, among an applicant and a patentee, was the first to invent the claimed subject matter. That mechanism is known as an interference, which is a "proceeding [] principally declared to permit a determination of priority." *Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 674 (Fed. Cir. 1991). As is oft-repeated, "[i]nterference practice is highly arcane and specialized," *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100 (Fed. Cir. 1994), and can be "virtually incomprehensible to the uninitiated," PATENTS AND THE FEDERAL CIRCUIT, *supra* p. 3, at 1152.

"An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 37 C.F.R. § 41.203. Either the patent applicant or the patent examiner may suggest an interference. *See id.* § 41.202. If the Director of the PTO agrees that an interference is warranted — *i.e.*, that "an application is made for a patent which would interfere with any pending application, or with any unexpired patent" — he may declare an interference and provide notice of such declaration to the applicants, or applicant and patentee, as the case may be. 35 U.S.C. §

135(a); *see also* 37 C.F.R. § 41.203.[2] The Board determines questions of priority of the inventions and may determine questions of patentability as well. 35 U.S.C. § 135(a).

As is relevant to the case at hand, once an interference is determined to be warranted and notice has been provided to the parties, a period is then set for the filing of preliminary statements and preliminary motions with the Board. *Gen. Instrument Corp., Inc. v. Scientific-Atlantic, Inc.*, 995 F.2d 209, 211 (Fed. Cir. 1993). "The 'preliminary' motions are usually a critical part of an interference." *Id.* at 212. In particular, as is of import in this case, a party may file a preliminary motion under 35 U.S.C. § 135(b)(1). Section 135(b)(1) motions are threshold motions that should be resolved before issues of priority and/or patentability are addressed, as resolution in favor of the movant would end the interference proceedings. *See Berman v. Housey*, 291 F.3d 1345, 1352 (Fed. Cir. 2002); *see also* 37 C.F.R. § 41.201.

"[S]ection 135(b) was enforced to codify a legal principle akin to laches, imposing 'a statute of limitations, so to speak, on interferences so that the patentee might be more secure in his property right.'" *In re Berger*, 279 F.3d 975, 982 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 764-65 (C.C.P.A. 1977)). It provides 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.

35 U.S.C. § 135(b)(1). As the Federal Circuit has explained, "[t]his provision requires an applicant wishing to provoke an interference with an issued patent to do so by filing a claim which is 'for the same or substantially the same subject matter' as a claim of the issued patent,

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[2] Pursuant to the implementing regulations, an administrative patent judge declares the patent interference on the Director's behalf. 37 C.F.R. § 41.203(b).

prior to one year from the issue date of the patent." *In re Berger*, 279 F.3d at 981.

To further its purpose of imposing a statute of limitations-like bar on interference proceedings, "[a]mended or supplemental claims added to a pending application after the one year anniversary of the issuance of a patent may benefit from the timely filings of original patent claims so long as the 'the later filed claim does not differ from an earlier claim in any 'material limitation.'" *Sears Ecological Applications Co., LLC v. MLI Assocs., LLC*, 652 F. Supp. 2d 244, 269 (N.D.N.Y. Sept. 1, 2009) (quoting *In re Berger*, 279 F.3d at 981); *see also In re Berger*, 279 F.3d at 982 ("To further that purpose, 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." *In re Berger*, 279 F.3d at 982. "If all material limitations of the copied claim are present in, or necessarily result from, the limitations of the prior claims, then the copied claim is entitled to the earlier effective filing date of those prior claims for purposes of satisfying 35 U.S.C. § 135(b)." *Id.*

B. Factual Background[3]

1. Cytologic Patent

Cytologic was granted the patent at issue on April 30, 2002, which issued from a patent application filed on November 20, 1999. Joint Appendix, Docket No. [25] (hereinafter "JA-1"), Ex. P10 (Board's Decision on Motions, dated Jan. 25, 2007) (hereinafter, "Bd. Dec."), at 4; *see*

[3] The parties do not dispute any of the specific factual findings made by the Board in the background section of its January 25, 2007 decision, as regarding the procedural history of this claim. Accordingly, the Court has relied on and cites primarily to the Board decision below, as supported by the Administrative Record, in reciting the factual background of this case.

also id., Ex. P1 (U.S. Patent 6,379,708 B1) (hereinafter "Cytologic patent"). The Cytologic Patent is directed to a method for enhancing an immune response by selectively removing immune system inhibitors present in the blood. *See* Cytologic Patent at cols. 11-4. This is accomplished by bringing the blood into contact with a binding partner (*e.g.*, antibodies or fragment of antibodies) capable of selectively binding to targeted immune system inhibitors. *Id.* at. col. 5, lines 26-34. This method is believed to be effective in the treatment of some types of cancer. *See id.* at col. 6, lines 15-34. In discussing Cytologic's patent, the critical date for purposes of 35 U.S.C. § 135(b)(1) — *i.e.,* one year from the date on which the patent was granted — is **April 30, 2003**. For convenience, the Court shall refer to this date as the "critical date."

2. Biopheresis' Patent Application

Given the importance of clearly demarcating which relevant events occurred before the critical date and which events occurred after, the Court divides the discussion of Biopheresis' patent application and related events accordingly.

i. Pre-critical date events.

Biopheresis filed the patent application now at issue on November 10, 2000, Patent Application 09/709,045. Bd. Dec. at 5. As originally filed, Biopheresis' application contained 16 claims. *Id.* at 12. On January 22, 2003, the application was amended to include new claims 17-22, which the application stated "essentially correspond to" the claims of Cytologic's patent. *Id.* at 12; *see also* JA-1, Ex. P3 (Biopheresis Amendment and Response to Office Action, dated Jan. 22, 2003) (hereinafter "Biopheresis Jan. 22, 2003 Amend."), at 6.[4] In particular, the parties'

[4] Given the parties' focus on claims 17-22, the Court limits its discussion of Biopheresis' patent application to these claims only and does not address the patent prosecution history of the remaining claims, which are not relevant to the parties' arguments as presented in their briefing.

dispute focuses on claims 17 and 22, which read as follows:

> 17. A method of enhancing an immune response to a patient comprising:
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> a. obtaining whole blood from the patient;
>
> b. separating out the plasm;
>
> c. contacting the plasma with antibody specifically binding to a targeted immune system inhibitor;
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> d. removing the inhibitor bound to the antibody from the plasma; and
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> e. returning the antibody-collected plasma to the patient.
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> * * *
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> 22. The method of claim 17 wherein the targeted immune system inhibitor is selected from the group consisting of soluble receptors for tumor necrosis factors alpha and beta.

Bd. Dec. at 12-13; Biopheresis Jan. 23, 2003 Amend. at 3-4.

ii. Post-critical date events.[5]

July 21, 2004 Office Action. On July 12, 2004, the patent examiner issued an Office Action rejecting Biopheresis' claims 17-22. In so doing, the patent examiner raised two grounds for rejection that are of particular importance to Cytologic's present motion. To understand the patent examiner's rejection of claims 17-22 and Cytologic's related argument, the Court must

[5] The parties focus exclusively on post-critical date events beginning in July 2004 and continuing thereafter, and the Court therefore focuses its discussion of the relevant factual background on these events as well. The Court notes, however, that the record reflects that between the post-critical date (*i.e.*, April 30, 2003) and the July 21, 2004 Office Action discussion above, Biopheresis and the patent examiner did take certain actions regarding claims 17-22. Specifically, on July 29, 2003, the patent examiner issued an Office Action rejecting claims 17-22 under 35 U.S.C. § 103(a) as unpatentable. Bd. Dec. at 13. Biopheresis replied on October 29, 2003, but did not make any amendments to claims 17-22. *Id.* The patent examiner again rejected claims 17-22 on February 25, 2004 as unpatentable. *Id.* On April 16, 2004, Biopheresis replied and made minor grammatical amendments to claims 17-22, which are not relevant to the pending dispute. *Id.* at 13; *see also* Defs.' Opp'n at 18, n. 6. More specifically, Biopheresis replaced "antibody" with "antibodies" and replaced "fragment" with "fragments." Bd. Dec. at 13. These various communications and amendments, however, are not material to the parties' arguments as presented in their briefing.

make a brief diversion once again into substantive patent law — specifically, 35 U.S.C. § 112. The first two paragraphs of section 112 provide, in relevant part, as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
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> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Perhaps somewhat unimaginatively, these paragraphs are referred to as "section 112, para. 1" and " section112, para. 2," respectively. The former looks into the adequacy of the claim's written description while the latter considers the indefiniteness of the claim language, each of which is a "distinct question[]." *Applic. of Cormany*, 476 F.2d 998, 999-1000 (C.C.PA. 1973) ("We regard indefiniteness of claim language and inadequate support for it in the specification to be distinct questions, and we shall therefore consider them separately, the former being a question of compliance with the second paragraph of § 112 and the latter a question of compliance with the first paragraph.") (internal citations omitted).

In this case, the patent examiner raised objections under both the first and second paragraph of section 112 in rejecting Biopheresis' claims 17-22. *First*, the patent examiner rejected claims 17-21 (but not claim 22) for failure to comply with the written description requirement pursuant to section 112, para. 1. JA-1, Ex. P4 (Patent Examiner's Office Action, dated July 12, 2004) (hereinafter "July 12, 2004 Office Action"), at 5. The patent examiner based his rejection on the fact that the "specification does not use the term 'targeted immune system inhibitor,' nor can said term be said to flow from the specification as originally filed." *Id.*

Rather, the specification was limited to methods of removing immune inhibitors *produced by tumors*. *Id.* The patent examiner therefore concluded that claims 17-21, which did not contain this limitation (*i.e.*, only immune inhibitors produced by tumors as opposed to all targeted immune system inhibitors), should be rejected under 35 U.S.C. § 112, para. 1. *Id.* Importantly, as the Board observed in its decision, "the examiner did not reject claim 22, which limited the targeted immune system inhibitor to soluble receptors for tumor necrosis factors alpha and beta, on this ground." Bd. Dec. at 14.

Second, the patent examiner rejected claims 17-22 under 35 U.S.C. § 112, para. 2, as indefinite. July 12, 2004 Office Action at 6. The examiner reasoned that while claim 17 "recites 'contacting the plasma with antibodies specifically binding to a targeted immune system inhibitor," the "specification does not use nor define the term 'immune system inhibitor,' hence the metes and bounds of the claim cannot be determined.'" *Id.* at 7.

Biopheresis' October 6, 2004 Amendment. Biopheresis subsequently amended claims 17-22 on October 6, 2004. Bd. Dec. at 15; JA-1, P5 (Biopheresis Amendment and Response to Office Action of July 12, 2004, dated Oct. 6, 2004) (hereinafter "Biopheresis Oct. 6, 2004 Amend."). Specifically, with respect to claim 17, Biopheresis amended step (c) by revising "contacting the plasma with antibodies specifically binding to a targeted immune system inhibitor" to read "contacting the plasma with antibodies or antibody fragments specifically binding to soluble cytokine receptor molecules which function as cytokine inhibitors." Bd. Dec. at 15; *see also* Biopheresis Oct. 6, 2004 Amend. at 4. In other words, the amended claim 17 read as follows (with added language underlined and deleted language struck out):

17. A method of enhancing an immune response to a patient comprising:
    a. obtaining whole blood from the patient;
    b. separating out the plasm;
    c. contacting the plasma with antibody or antibody fragments specifically binding to ~~a targeted immune system inhibitor~~ soluble cytokine receptor molecules which function as cytokine inhibitors;
    d. removing the inhibitor bound to the antibody from the plasma; and
    e. returning the antibody-collected plasma to the patient.

Biopheresis Oct. 6, 2004 Amend. at 4. Claim 22, which is dependent on claim 17, was correspondingly revised to reflect the changes in claim 17, as follows (deleted language struck out):

22. The method of claim 17 wherein the ~~targeted immune system~~ inhibitor is selected from the group consisting of soluble receptors for tumor necrosis factors alpha and beta.

Id. at 5; *see also* Bd. Dec. at 15.

January 6, 2005 Office Action. In the next Office Action, dated January 6, 2005, the patent examiner indicated that amended claims 17-22 were allowable. Bd. Dec. at 15; *see also* JA-1, Ex. P6 (Patent Examiner's Office Action mailed Jan. 6, 2005).

Biopheresis' May 6, 2005 Amendment. Thereafter, on May 6, 2005, Biopheresis filed another amendment with the PTO, cancelling claims 1-22 and adding claims 23-41. Claims 23-41 are patterned after the claims in Cytologic's patent in order to provoke an interference. Bd. Dec. at 15; *see also* JA-1, Ex. P7 (Biopheresis Amendment under C.F.R. § 1.116 to Office Action of January 6, 2005, dated May 6, 2005) (hereinafter, "Biopheresis May 6, 2005 Amend."), at 8. To that end, Biopheresis submitted a "Suggestion of Interference," indicating that "it believes that its claims 23-41 interfere with claims 1-44 of the [Cytologic] patent." JA-1, Ex. P8

(Biopheresis Suggestion of an Interference under 37 C.F.R. 41.202, dated May 6, 2005) (hereinafter "Suggestion of Interference").

Claims 23-41 have not been amended. Bd. Dec. at 15. As is of relevance to the parties' dispute, claim 23 reads as follows:

> 23. A method of enhancing an immune response in a patient having soluble cytokine receptor molecules in the blood which inhibit the immune response, the method comprising of:
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> a. obtaining whole blood from the patient;
>
> b. separating plasma from the blood;
>
> c. contacting the plasma with at least one cytokine receptor inhibitor selected from the group consisting of antibodies or antibody fragments binding to soluble cytokine receptor molecules, and cytokine molecules and epitopes thereof binding to soluble cytokine receptor molecules;
>
> d. removing soluble cytokine receptor molecules bound to the cytokine receptor inhibitor from the plasma; and
>
> e. returning the plasma from which the soluble cytokine receptor molecules have been removed to the patient.

Id. at 16; Biopheresis May 6, 2005 Amend. at 2.

3. January 12, 2006 Interference

On January 12, 2006, the Board declared an interference between the Cytologic patent and the Biopheresis patent application. Bd. Dec. at 4; *see also* JA-1, Ex. P2 (Declaration of Interference No. 105,413) (hereinafter, "Decl. of Interference"). The sole count was defined as claim 1 of the Cytologic patent and claim 23 of the Biopheresis patent application. *Id.* at 4. In addition, claims 1-44 of the Cytologic patent and claims 23-41 of the Biopheresis patent were identified as corresponding to the count, which means that all of these claims are affected by the ultimate judgment on the interference. *See id.*

As is relevant to the instant Memorandum Opinion, Cytologic filed a preliminary motion

arguing that Biopheresis claims 23-41 are barred under section 135(b)(1). *See* JA-1, Ex. P9 (Cytologic Section 135(b)(1) motion, titled "Howell Substantive Motion 1," dated Feb. 21, 2006) (hereinafter "Section 135(b)(1) Motion"); *see also* Bd. Dec. at 10. Biopheresis did not file an opposition; instead, Biopheresis filed a motion requesting that, in the event Cytologic's Section 135(b)(1) Motion was granted, Biopheresis be permitted to substitute proposed claims 42-46 for claims 23-41.[6] Bd. Dec. at 3, 10. The Board heard oral arguments on Cytologic's Section 135(b)(1) Motion on November 9, 2006. *Id.* at 4.

On January 25, 2007, the Board issued a decision that, in relevant part, denied Cytologic's Section 135(b)(1) Motion. As set forth therein, the Board held, *inter alia*, that Cytologic, as the moving party, bore the burden of proving that Biopheresis' involved claims 23-41 are barred under 35 U.S.C. § 135(b)(1) and that Cytologic had "not satisf[ied] its burden of proving that there is a material difference between the subject matter now claimed and that claimed prior to the § 135(b) critical date." *Id.* at 17. In so doing, the Board rejected Cytologic's argument that "the replacement of 'targeted immune system inhibitor' in claim 17 (a pre-critical date claim) with 'soluble cytokine receptor molecules, and cytokine molecules and epitopes thereof binding to soluble receptor molecules' in claim 23 (a post-critical date claim) renders the latter recitation a material limitation." *Id.* at 16. Cytologic had argued that the limitation was material because the amended language "was necessary to overcome the examiner's [July 12, 2004] rejection, which was based on the notion that the term 'targeted system inhibitor' lacks

[6] At oral argument, counsel for Biopheresis emphasized that it declined to file an opposition to Cytologic's Section 135(b)(1) "not [as] a concession of the merits," but "rather to simplify and streamline the proceedings" through amendment of its claims that "would render unnecessary getting into many of the issues those original motions sought to raise." JA-2, Ex. D1 (Transcript of November 9, 2006 Oral Arguments) at 8:6-17.

written description in the specification, as originally filed, in violation of 35 U.S.C. § 112, para. 1." *Id.* The Board did not agree, concluding that:

> [Cytologic]'s argument would have some force *if* claim 17 were the only pre-critical date claim. But that is not the case. Here, we determine that claim 22 is also a pre-critical date claim. Claim 22 was never rejected as being in violation of the written description of 35 U.S.C. § 112, para. 1. . . . In this regard, claim 22 limited the targeted immune system inhibitor to soluble receptors for tumor necrosis factors alpha and beta. [Cytologic] failed to address how and why the differences between any of the post-critical date claims 23-41, on one hand, and pre-critical date claim 22, on the other hand, constitute material differences.
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> ***
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> At issue is whether [Biopheresis]'s post-critical date claims, which interfere with the claims of [Cytologic]'s patent, are *not* entitled to the filing date of [Biopheresis]'s pre-critical date claims. If a later filed claim involved in interference does not differ from an earlier filed claim in any material limitation, then a rejection under 35 U.S.C. § 135(b)(1) of that claim is not appropriate. Here, [Cytologic] has not established that the differences between the post-critical date involved claims and all pre-critical date claims, in particular claim 22, were in fact necessary for patentability.

Id. at 17-18. The Board therefore concluded that Cytologic had failed to show that claims 23-41 were barred under section 135(b)(1). Cytologic now challenges that decision.

4. The Instant Lawsuit

On June 6, 2008, Cytologic filed the above-captioned lawsuit seeking review of the Board's decisions in the interference pursuant to 35 U.S.C. § 146. *See generally* Compl., Docket No. [1]. At the Court's request, the parties filed a joint status report proposing a schedule for proceeding in this matter. Jt. Status. Report, Docket No. [17]. Cytologic indicated its intent to file a summary judgment motion under 35 U.S.C. § 135(b)(1), which, if granted, would result in a voiding of the Board's decision. *See id.* at 2. Cytologic therefore proposed that the parties brief, and the Court resolve, the section 135(b)(1) issue before proceeding with discovery. *Id.* at

2. Biopheresis indicated that while it "[did] not object to early presentation of Plaintiffs' proposed dispositive motion based on § 135(b)," it took the position that the parties should proceed to brief disputes as to the scope of discovery in this case. *Id.* at 3-4. The Court ultimately agreed with Cytologic's proposed schedule and set a schedule for proceeding with Cytologic's motion for summary judgment on the threshold section 135(b)(1) question, deferring consideration of discovery issues until after the motion is resolved. *See* 11/13/08 Order, Docket No. [18].

Pursuant to that schedule, Cytologic filed the now-pending Motion for Summary Judgment to Vacate Interference Pursuant to 35 U.S.C. § 135(b)(1) and Request for Oral Hearing. *See* Pls.' MSJ, Docket No. [20]. Biopheresis filed an opposition, *see* Defs.'Opp'n, Docket No. [21], and Cytologic has since filed its reply, *see* Pls.' Reply, Docket No. [23]. In addition, the parties jointly moved for an order entering the entire administrative record of the interference proceeding below as part of the record in this case*, see* Docket No. [22], which the Court granted, *see* 12/31/08 Min. Order. The parties have also filed their Joint Appendix of the Administrative Record. *See* Docket Nos. [25] & [26]. In addition, after principal briefing had been completed, the Court issued a minute order directing Cytologic to file a supplemental notice, *see* 12/16/09 Min. Order, which notice Cytologic has timely filed, *see* Pls.' Notice, Docket No. [28]. The Court provided Biopheresis an opportunity to respond to Cytologic's supplemental notice and also invited Biopheresis to file a sur-reply addressing a particular argument that Cytologic had raised for the first time in its reply, *see* 12/22/09 Min. Order, which it has now done, *see* Defs.' Sur-Reply. Cytologic subsequently filed an unopposed motion for leave to file a targeted response to Biopheresis' sur-reply, which the Court granted. *See* 1/15/10

Min. Order. Accordingly, the parties' briefing is complete, and the matter is therefore ripe for review and resolution by the Court.[7]

II. LEGAL STANDARD

A. Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56, a party is entitled to summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Tao v. Freeh*, 27 F.3d 635, 638 (D.C. Cir. 1994). Under the summary judgment standard, the moving party bears the "initial responsibility of informing the district court of the basis for [its] motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits which [it] believe[s] demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In response, the non-moving party must "go beyond the pleadings and by [its] own affidavits, or depositions, answers to interrogatories, and admissions on file, 'designate' specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal citations omitted).

Although a court should draw all inferences from the supporting records submitted by the nonmoving party, the mere existence of a factual dispute, by itself, is insufficient to bar summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To be material, the

[7] As the Court concludes that the issues presented in Cytologic's pending motion may be resolved on the extensive briefing filed by the parties, an oral hearing is unnecessary and the Court shall therefore DENY Cytologic's request that the Court hold oral arguments on its motion.

factual assertion must be capable of affecting the substantive outcome of the litigation; to be genuine, the issue must be supported by sufficient admissible evidence that a reasonable trier-of-fact could find for the nonmoving party. *Laningham v. U.S. Navy*, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987); *Liberty Lobby*, 477 U.S. at 251 (the court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law"). "If the evidence is merely colorable, or is not sufficiently probative, summary judgment may be granted." *Liberty Lobby*, 477 U.S. at 249-50 (internal citations omitted). "Mere allegations or denials in the adverse party's pleadings are insufficient to defeat an otherwise proper motion for summary judgment." *Williams v. Callaghan*, 938 F. Supp. 46, 49 (D.D.C. 1996). The adverse party must do more than simply "show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986). Instead, while the movant bears the initial responsibility of identifying those portions of the record that demonstrate the absence of a genuine issue of material fact, the burden shifts to the non-movant to "come forward with 'specific facts showing that there is a *genuine issue for trial*.'" *Id.* at 587 (citing Fed. R. Civ. P. 56(e)) (emphasis in original).

B. Standard of Review Under 35 U.S.C. § 146

Cytologic seeks review of the Board's decision in the interference proceeding below pursuant to 35 U.S.C. § 146, *see* Compl. ¶ 1, which provides that "[a]ny party to an interference dissatisfied with the decision of the Board . . . on the interference, may have remedy by civil action," 35 U.S.C. § 146. An action under section 146 "may be instituted against the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision

complained of" — in this case, Biopheresis. *Id.* Moreover, where, as here, there is "an adverse party residing in a foreign country, the United States District Court for the District of Columbia shall have jurisdiction and may issue summons against the adverse parties." *Id.*

Judicial review under section 146 is "described as a hybrid of an appeal and a trial *de novo*." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997). In such actions, the record below may be admitted by either party, but the parties may "take further testimony." *See* 35 U.S.C. § 145; *see also Agilent Tech., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009). "Questions of law are reviewed *de novo*, but the underlying factual determinations made by the Board are reviewed for clear error." *Abbott GMBH & Co. KG v. Yeda Research & Dev. Co, Ltd.,* 576 F. Supp. 2d 44, 49 (D.D.C. 2008) (citing *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed. Cir. 2000)). If, however, the district court accepts new evidence not previously before the Board, the Court must make *de novo* factual findings for issues on which the court accepts new evidence. *Id.* The Court notes that for purposes of Cytologic's pending motion, the parties have relied solely on the administrative record and have not submitted new evidence.

III. DISCUSSION

As indicated above, Cytologic's pending motion for summary judgment focuses solely on the Board's decision to deny Cytologic's preliminary Section 135(b)(1) Motion. The Court emphasizes at the outset that, in challenging the Board's decision, Cytologic has chosen not to dispute the majority of the Board's underlying findings of fact and conclusions of law as set forth in the Board's lengthy discussion of Cytologic's Section 135(b)(1) Motion. *See* Bd. Dec. at 10-23 (portion of the Board Decision discussing Cytologic's Section 135(b)(1) Motion). Cytologic

has instead presented a very narrow and targeted challenge to the Board's decision. Specifically, Cytologic argues that the Board's decision is in error for only two discrete reasons, as outlined below, either of which Cytologic asserts require reversal of the Board's decision and final judgment in favor of Cytologic. The Court's discussion is therefore similarly limited in scope, addressing only the two specific Board rulings that Cytologic now claims are in error.

First, Cytologic argues that the Board erroneously allocated the burden of proof with respect to the question of materiality under section 135(b)(1). According to Cytologic, in order to succeed on its Section 135(b)(1) Motion, it needed to show only that Biopheresis claims 23-41 — which formed the basis of the interference proceedings — were filed more than one year after Cytologic's patent was issued. Once this showing was made, Cytologic had demonstrated that the claims were barred under section 135(b)(1) absent proof by Biopheresis that claims 23-41 did not differ in any material limitation from its pre-critical date claims 17-22, such that the claims could benefit from the earlier filing date. Because Biopheresis did not file an opposition to Cytologic's Section 135(b)(1) Motion, Cytologic contends that Biopheresis failed to meet its burden of proof with respect to materiality and the Board should have found that claims 23-41 were therefore barred under section 135(b)(1). For the reasons set forth below, the Court ultimately finds that Cytologic's argument lacks merit and concludes that the Board correctly held that Cytologic — and not Biopheresis — bore the burden of demonstrating that Biopheresis claims 23-41 differed in a material limitation from claims 17-22.

Second, Cytologic argues that even if the Board properly allocated the burden of proof, the Board nonetheless erred when it held that Cytologic had not demonstrated that claims 23-41 differed in a material limitation from claims 17-22 because it ignored a key fact in reaching this

determination — namely, that the patent examiner rejected claims 17-22 under section 112, para. 2. Cytologic contends that the patent examiner's rejection of the claims under section 112, para. 2 conclusively demonstrates that the claims differ in a material limitation, and the Board therefore acted in error when it failed to consider the effect of the section 112, para. 2 rejection in denying Cytologic's Preliminary Section 135(b)(1) Motion. As is discussed in more detail below, the Court finds that Cytologic did not present this specific argument to the Board and is therefore precluded from doing so now.

A. Burden of Proof

First, Cytologic argues that the Board erred when it required Cytologic to bear the burden of proving that Biopheresis' involved claims (23-41) materially differed from its pre-critical date claims (17-22). According to Cytologic, it should have been required to show only that Biopheresis claims 23-41 had been filed after the critical date — *i.e.*, more than one year after Cytologic's patent had been issued — and that once this showing was made, the burden then shifted to Biopheresis to show that these claims do *not* differ materially from the earlier claims (17-22), such that they may benefit from the earlier filing date pursuant to section 135(b)(1). Pls.' MSJ at 7-8. Because Biopheresis chose not to file an opposition to Cytologic's motion, but instead filed a motion seeking leave to file further amendments to the claims, Cytologic argues that Biopheresis clearly failed to meet its burden, and the Board therefore should have granted Cytologic's section 135(b) motion. *Id.* at 8.

As the Court understands Cytologic's argument, it does not dispute the Board's holding pursuant to 37 C.F.R. § 41-121(b) that Cytologic, "[a]s the moving party, [] bears the burden of proving that [Biopheresis]'s involved claims 23-41 are barred under U.S.C. § 135(b)(1)." Bd.

Dec. at 10. Nor could it, as the regulations make clear that Cytologic, as the movant, properly bore the burden of proof to show that it was entitled to the remedy requested. Specifically, 37 C.F.R. § 41.121(b) provides that "[t]he party filing the motion has the burden of proof to establish that it is entitled to the requested relief."[8] In addition, although not cited by the Board, 37 C.F.R.§ 41.208(b) — which governs the requirements for substantive motions filed in patent interferences (as opposed to contested cases in general) and serves to supplement the general requirements for motions filed in contested cases as set forth in 37 C.F.R. § 41.121 — further specifies that, "[t]o 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." 37 C.F.R. § 41.208(b).

Rather, it appears that Cytologic disagrees only as to what showing it was required to make in order to meet that burden of proof. Specifically, the Board held that Cytologic, as the movant, had the burden to show not only that the involved claims (23-41) were filed after the post-critical date — a fact that is undisputed — but also that those claims materially differed from the pre-critical date claims 17-22. *See* Bd. Dec. at 17 ("[Cytologic's] assertion does not satisfy its burden of proving that there is a material difference between the subject matter claims now and that claimed prior to the § 135(b) critical date."). Cytologic disagrees, arguing that it should have been required to prove only that Biopheresis' involved claims (23-41) were filed after the post-critical date. According to Cytologic, once it made that showing, it satisfied its

[8] While section 41.121(b) explicitly applies only to "contested cases," the regulations make clear that "[a] patent interference is a contested case" and is therefore subject to the general procedures governing contested cases, including the procedures set forth in 37 C.F.R. § 41.121(b). 37. U.S.C. § 41.200(a).

burden of proof under section 135(b)(1), and it was then up to Biopheresis, as the patent applicant, to show that its post-critical date claims are nonetheless permissible because they do not materially differ from pre-critical date claims. Pls.' MSJ at 7-8. The Court, however, does not agree. As explained below, the Court finds that the Board correctly held that Cytologic, as the movant, was required to prove that Biopheresis' post-critical date claims were barred by section 135(b)(1) — which necessarily included demonstrating that the claims contained a material limitation not found in the pre-critical date claims, such that they could not benefit from the earlier claims' pre-critical date filing.

As an initial matter, there is no dispute that a patent applicant who seeks declaration of an interference based on claims filed after the relevant critical date — *i.e.,* more than a year after the issuance of the patent at issue — bears the burden in the first instance of demonstrating that its late-filed claims are not barred by section 135(b)(1). As Biopheresis argues, and as Cytologic does not dispute, the party initially requesting the interference must demonstrate that it is entitled to priority of claims, and the patent examiner must be satisfied that the conditions for an interference have been met. *See* Defs.' Opp'n at 10-11. Accordingly, in this case, it is undisputed that Biopheresis initially bore the burden of proving to the patent examiner that its late filed claims (23-41) do not differ in any material limitation from its timely claims (17-22), such that section 135(b)(1) did not bar the examiner from declaring an interference in the first instance based on Biopheresis claims 23-41.

Once an interference has been declared, however, the parties disagree as to who bears the burden of showing materiality (or immateriality) when a preliminary section 135(b)(1) motion is filed during interference proceedings. Cytologic argues that the patent applicant at all times

retains the burden of showing an absence of materiality, while Biopheresis takes the position that, once an interference has been declared, the party seeking to challenge that decision through a section 135(b)(1) motion bears the burden of proving materiality. Neither party has provided the Court with any case law directly addressing the question of the burden of proof under 37 C.F.R. § 41.121(b) when a party files a section 135(b)(1) motion during an interference proceeding, nor is the Court aware of any such authority. Although Cytologic cites to the decision in *Regents of the University of California v. University of Iowa Research Foundation*, 455 F.3d 1371 (Fed. Cir. 2006), that opinion does not specifically discuss or address a party's burden of proof on a preliminary section 135(b)(1) motion after an interference has been declared. Similarly, Cytologic relies heavily on *Parks v. Fine*, 773 F.2d 1577 (Fed. Cir. 1985), but that decision makes no reference to the current regulatory scheme specifically allocating the burden of proof on the party proponent and indeed was decided well before the relevant regulations regarding the burden of proof took effect. The particular question at hand thus appears to be an issue of first impression.

Nonetheless, Cytologic maintains that *Parks* governs the outcome of this Court's decision — notwithstanding that Cytologic concedes the decision was issued well before the current regulations were promulgated. Citing to the well established principle that the PTO lacks substantive rulemaking authority to overturn legal precedent, Cytologic argues that the PTO was without authority to issue regulations contradicting the holding in *Parks* and therefore, to the extent the holding in *Parks* differs from the current regulations, the decision in *Parks* controls. *See* Pls.' Sur-Surreply at 1-2 (citing *Koniklijke Philips Elec. N.V. v. Cardiac Sci. Operating Co.*, __ F.3d __, Civ. Act. No. 2009-1241, 2010 WL 10913 (Fed. Cir. Jan. 5, 2010); *Agilent Tech.,*

Inc. v. Affymetrix, Inc., 567 F.3d 1366 (Fed. Cir. 2009); *Wyeth v. Kappos*, __ F.3d __, Civ. Act. No. 2009-1120, 2010 WL 27184 (Fed. Cir. Jan. 7, 2010)). This argument is without merit. As the cases cited by Cytologic make clear, although the PTO does not have authority to issue *substantive* rules, it does have the authority to issue "*procedural* regulations regarding the conduct of proceedings before the agency." *Wyeth*, 2010 WL 27184, at *3 (internal quotations marks omitted) (emphasis added); *see also Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (PTO Commissioner is authorized "to promulgate regulations directed only to 'the conduct of proceedings in the [PTO];' it does NOT grant the Commission the authority to issue substantive rules") (quoting *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)). As regulations governing the burden of proof during interference proceedings are procedural — not substantive — the PTO was therefore well within its authority to issue the regulations at issue. *Cf. Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) (describing rules regarding burden of proof in the interference proceeding as procedural in nature); *Kubota v. Shibuya*, 999 F.2d 517, 521 (Fed. Cir. 1993) (discounting precedent decided under the old interference rules and upholding PTO's issuance of new regulations that changed burden of proof in interference proceedings). The Court therefore rejects Cytologic's position that the holding in *Parks* governs the specific question at issue in this case.

The issue presented by the parties thus appears to be one of first impression and neither party has directed the Court to any binding precedent that governs resolution of this question. The Court, however, is not without guidance. Careful review of the relevant case law and the present regulatory scheme persuade the Court that Biopheresis has the better argument, for the reasons set forth below.

As discussed above, the regulations make clear that "[t]he party filing the motion has the burden of proof to establish that it is entitled to the requested relief," 37 C.F.R. § 41.121(b), and that, "[t]o be sufficient, a motion must provide a showing, supported with appropriate evidence, such that, if unrebutted, it would justify the relief sought," *id.* § 41.208(b). In this case, Cytologic's preliminary Section 135(b)(1) Motion sought to prove that Biopheresis' later filed claims were time barred pursuant to that section, such that the interference should be dissolved. Where, as here, the claims at issue are supplemental or amended claims filed more than one year after the challenged patent was granted, section 135(b)(1) as construed by the relevant case law bars such claims unless they are "entitled to the earlier effective date of prior claims in an application." *In re Berger*, 279 F. 3d at 982. Whether a post-critical date claim may benefit from the earlier filing date in turn depends upon showing that the later filed claim does not differ from an earlier claim in any "material limitation." *Id.* "If all material limitations of the copied claim are present in, or necessarily result from, the limitations of the prior claims, then the copied claim is entitled to the earlier effective filing date of those prior claims for purposes of satisfying 35 U.S.C. § 135(b)." *Id.* In other words, post-critical date claims are entitled to the earlier filing date of pre-critical date claims and are not barred by section 135(b) if they "do[] not differ from the prior claims in any material limitation." *Id.* From this flows the eminently reasonable conclusion that in order to show that it was entitled to the relief sought — *i.e.*, that Biopheresis' post-critical date claims (23-41) are barred under section 135(b)(1) — Cytologic was required to prove that those claims could not benefit from the earlier filing date of the pre-critical claims. In order to do so, Cytologic had to show that the post-critical date claims differed from the earlier filed claims (17-22) in a material limitation. It was not enough to simply point the Board to the

undisputed fact that Biopheresis' post-critical date claims were filed more than one year after Cytologic's patent was granted. Case law makes clear that such claims may nonetheless serve as the basis for an interference if they do not differ in a material limitation from Biopheresis' timely pre-critical date claims.

Cytologic's argument to the contrary appears to be based on the premise that because the statute itself "does not contain any language regarding material differences between post- and pre-critical date claims," Cytologic needed to prove only that the Biopheresis' claims were filed after the critical date as set forth in section 135(b)(1) in order to show that the claims are time barred under the statute. Pls.' MSJ at 7-8. But this line of reasoning ignores well established case law construing section 135(b)(1) to bar only those amended or supplemental claims that differ from previous, timely claims in a material limitation. Just as a proponent seeking to provoke an interference bears the burden of proving that a later filed claim does not materially differ from an earlier filed claim, a proponent seeking to dissolve an interference based on section 135(b)(1) bears the burden of proving that a later filed claim *does* materially differ from an earlier filed claim. Indeed, Cytologic's position that the movant seeking to dissolve an interference proceeding pursuant to section 135(b)(1) need only show that the involved claims were filed after the one year critical date makes little sense. As discussed above, the patent examiner must be satisfied that the conditions for an interference have been met before an interference is declared. This in turn requires that the party requesting the interference sufficiently demonstrate that any claims filed after the one year critical date are able to benefit from the earlier filing date of prior claims, such that they are not barred by section 135(b)(1). It would be far from efficient or logical if the interference could then be dissolved simply upon a

showing that the involved claims were filed after the one year critical date — a fact of which all parties and the Board are surely aware.

A review of recent case law supports this conclusion. Although, as discussed above, neither the parties nor the Court has identified a case in which the parties directly litigated the specific question at hand, at least one court has proceeded on the understanding — accepted by all parties — that the party moving for dissolution of an interference pursuant to section 135(b)(1) bears the burden of proving "that the pre-critical date claims did not include the same material limitations stated within the post-critical date claims." *Sears Ecological Applications*, 652 F. Supp. 2d at 270. Moreover, recent decisions by the Federal Circuit confirm the general trend under the new PTO regulatory scheme to require the party seeking to dissolve an interference to bear the burden of showing that it is entitled to the requested relief. *See, e.g., Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1101 (Fed. Cir. 1994) ("once an interference has been declared, the burden is on a party who seeks to change the nature of the interference to take action by means of a suitable motion to persuade the examiner-in-chief or the Board of the merits of his or her position"); *Kubota*, 999 F.2d at 522 ("It seems to us that, while the burden initially may be on a party seeking to provide an interference, or seeking to obtain entitlement to a priority date, once an interference has been declared and a party seeks to change the status of the parties by motion, the burden is then on the movant under the new rules, rather than on the party originally provoking the interference or obtaining entitlement."); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1121 (Fed. Cir. 2004) ("Thus, once [the party seeking to provoke an interference] convinced the examiner he was entitled to an interference, that decision was presumed to be correct, and [the party seeking to dissolve the interference] bore the burden of proving that it was

incorrect by a preponderance of the evidence."). Although, as Cytologic notes, these cases involve different preliminary substantive motions and do not directly address the burden of proof in filing a preliminary section 135(b)(1) motion, the logic behind these decisions is persuasive and further supports finding that Cytologic bore the burden of showing that the interference was wrongly invoked in the first instance. In order to do so, Cytologic was required to show that Biopheresis' later filed claims did not in fact benefit from the timely filing date of its earlier claims. Accordingly, the Court finds that the Board correctly held that Cytologic — and not Biopheresis — bore the burden of demonstrating that Biopheresis claims 23-41 differed in a material limitation from claims 17-22. Cytologic's motion is therefore DENIED to the extent it argues that the Board incorrectly allocated the burden of proof with respect to Cytologic's preliminary Section 135(b)(1) Motion.

B. Materiality Under Section 135(b)(1)

Second, Cytologic contends that even if the Board properly held that it bore the burden of proof on materiality, Cytologic nonetheless demonstrated that Biopheresis claims 23-41 differed in a material limitation from claims 17-22, and the Board therefore erred when it found to the contrary. Cytologic's argument on this point is a narrow one. Specifically, Cytologic argues that the Board erroneously "neglected to consider" that claim 22 had been rejected by the patent examiner for being indefinite under 35 U.S.C. § 112, para. 2. Pls.' MSJ at 9. Unfortunately for Cytologic, it did not present this specific argument to the Board in the interference proceedings below and is therefore foreclosed from doing so now.

With respect to the issue of materiality, Cytologic argued in its preliminary Section 135(b)(1) Motion that Biopheresis claim 17 differed from Biopheresis claim 23 in a material

limitation because the former contained the phrase "targeted immune system inhibitor" while the latter had been amended to replace that language with the phrase "soluble cytokine receptor molecules, and cytokine molecules and epitopes thereof binding to soluble receptor molecules." Section 135(b)(1) Mot. at 11. According to Cytologic, because Biopheresis amended the language in claim 23 in order to address the patent examiner's rejection of claim 17 "as not supported by the specification" under section 112, para. 1, the amendment was "necessary for patentability" and therefore material under Federal Circuit case law. *Id.* at 11. Cytologic's materiality argument thus focused on the fact that Biopheresis had added the phrase "soluble cytokine receptor molecules" to claim 23 in response to the patent examiner's rejection of claim 17 under to section 112, para. 1 (written description). *See id.*

Cytologic's materiality argument was thus based solely on the patent examiner's section 112, para. 1 (written description) rejection. Cytologic did not raise a similar materiality argument based on the patent examiner's rejection under section 112, para. 2 (indefiniteness). *See id.* When asked to provide the Court with record citations to any discussion of section 112, para. 2 in its briefing below, Cytologic responded that it had "raised that argument at page 11, lines 11-20 of the [] Section § 135(b)(1) Motion before the Board." Pls.' Not. at 1. The cited portion of Cytologic's Section 135(b)(1) Motion, however, does ***not*** contain any discussion of section 112, para. 2 or of the patent examiner's rejection of claims 17-22 as indefinite — but instead refers ***only*** to section 112, para. 1 and the patent examiner's rejection of claim 17 as "not supported by the specification." *See* Section 135(b)(1) Mot. at 11. The relevant provision of Cytologic's brief below states in full:

The Examiner of [Biopheresis] Claim 17 required removal of the recitation of

> "targeted immune system inhibitor" from the claim, because it was not supported by the specification. (Material Fact 39). In Claim 23, [Biopheresis] replaced the recitation of "targeted immune system inhibitor" used in Claim 17 with "soluble cytokine receptor molecules, and cytokine molecules and epitopes thereof binding to soluble receptor molecules." (Material Fact 40). The phrase added to Claim 23 of "soluble receptor molecules" is a material limitation compared to "targeted immune system inhibitor" which was recited in [Biopheresis] Claim 17, because it was an amendment necessary for patentability. Only upon adding Claims 23-41 and canceling Claims 17-22 over the claims found to be reliable. (See also Material Fact 41).

See id. at 11 (lines 11-20). As careful review of this passage confirms, Cytologic's argument in its briefing below was based solely on the patent examiner's rejection of claim 17 as "not supported by the specification" — a section 112, para. 1 written description argument. The briefing makes no mention of, nor includes any argument based on, the patent examiner's rejection of claims 17-22 under section 112, para. 2 for indefiniteness. *See id.* Similarly, the specific statements of material fact cited to in the quoted passage focus solely on the patent examiner's rejection of claim 17 as "not supported by the specification," and contain no facts relating to the patent examiner's section 112, para. 2 rejection for indefiniteness. *See id.*, App. B, ¶¶ 39-41.

Cytologic's only argument to the Board, then, was its contention that Biopheresis' post- and pre-critical date claims differed in a material limitation because the phrase "soluble cytokine receptor molecules" was added to claim 23 in order to overcome the patent examiner's rejection of claim 17 under section 112, para. 1 rejection. The Board ultimately rejected this argument, finding that claim 22 was also a pre-critical date claim and that it, unlike claim 17, had not been rejected by the patent examiner under section 112, para. 1. Because Cytologic's argument with respect to the patent examiner's section 112, para. 1 rejection did not apply to claim 22 and

Cytologic had not presented any alternative argument addressing claim 22 in particular, the Board held that Cytologic had failed to prove that Biopheresis' post-critical date claims are not entitled to claim 22's earlier filing date. *See* Bd. Dec. at 17-18. Given that Cytologic presented the Board with an argument based on the patent examiner's rejection of claim 22 under section 112, para. 2, it is difficult to understand how the Board erred, as Cytologic contends, when it "neglected to consider" that very argument — an argument that was never before it. Regardless, Cytologic's failure to raise any such argument in the interference proceedings is fatal to its efforts to do so now.

Case law makes clear that a party may not raise new issues on appeal that were not fully presented at the Board level. *Conservolite*, 21 F.3d at 1102; *see also In re Watts*, 354 F.3d 1362, 1367-68 (Fed. Cir. 2004). "In a proceeding before the Board the applicant is given a full 'opportunity to bring forth the facts thought necessary to support his or her position.'" *In re Watts*, 354 F.3d at 1367 (quoting *In re Gartside*, 203 F.3d 1305, 1314 (Fed. Cir. 2000)). "[T]he parties to an interference must make complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources." *Conservolite*, 21 F.3d at 1102. Thus, while "Section 146 authorizes the district court on review to accept new testimony," such testimony must relate to "issues raised by the parties during the proceedings below or by the Board's decision." *Id.* "In order for an issue to be raised adequately in an interference proceeding so that it qualifies for evidentiary review in a section 146 proceeding, more is required than passing reference to the subject during the course of the interference proceeding. For the most part, parties should raise issues in the manner clearly specified in the PTO's interference regulations, that is through preliminary motions, motions to

correct inventorship, belated motions delayed for good cause or opposition to these motions." *Gen. Instrument Corp., Inc. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993).

Here, Cytologic did not raise any materiality argument regarding the patent examiner's rejection of claims 17-22 under section 112, para. 2 at Board level. Although Cytologic generally argued that Biopheresis' post-critical date claims are barred under section 135(b)(1) because they contain material limitations not present in Biopheresis' pre-critical date claims, its failure to raise the specific argument now at issue precludes consideration of that argument in this section 146 action. *See Sears Ecological Applications*, 652 F. Supp. 2d at 271 ("Although the overarching issue of whether [defendant]'s post-critical date claims relate back to its pre-critical date claims was presented before the Board, [plaintiff]'s failure to raise an argument at the Interference with respect to [a particular] limitation issue bars present consideration of that argument in this § 146 action."). Accordingly, Cytologic's motion is DENIED to the extent it argues that the Board erred when it failed to consider the patent examiner's indefiniteness rejection of claim 22 under 35 U.S.C. § 112, para. 2 (indefiniteness).

IV. CONCLUSION

For the reasons set forth above, Cytologic's [20] Motion for Summary Judgment to Vacate Interference Pursuant to 35 U.S.C. § 135(b)(1) and Request for Oral Hearing is DENIED. An appropriate Order accompanies this Memorandum Opinion.

Date: January 15, 2010

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge