In The
United States Court of Appeals
For The Federal Circuit

IN RE: URVASHI BHAGAT,

Appellant.

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD IN APPLICATION NO. 12/426,034.

BRIEF OF *AMICI CURIAE* IN SUPPORT OF APPELLANT'S COMBINED PETITION FOR REHEARING OR REHEARING *EN BANC*

H. Dickson Burton
Allen C. Turner
TRASKBRITT, P.C.
230 South 500 East, Suite 300
Post Office Box 2550
Salt Lake City, Utah 84110
(801) 532-1922
hdburton@traskbritt.com
acturner@traskbritt.com

Counsel for Amici Curiae

Dated May 9, 2018

THE LEX GROUP^{DC} ♦ 1050 Connecticut Avenue, N.W. ♦ Suite 500, #5190 ♦ Washington, D.C. 20036
(202) 955-0001 ♦ (800) 856-4419 ♦ www.thelexgroup.com

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *amici curiae* certifies the following:

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

U.S. Inventor, LLC, Norman Abt, PhD, Margaret Betsock, MBA, Deborah Verity, C.P.G., Margaret Blackford, Jairam KP Vanamala, PhD and Sean McGhee, M.D.

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

Not applicable

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:

None

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 (and who have not or will not enter an appearance in this case) are:

H. Dickson Burton
Allen C. Turner
TRASKBRITT, P.C.
230 South 500 East, Suite 300
Post Office Box 2550
Salt Lake City, UT 84110
Telephone: (801) 532-1922
hdburton@traskbritt.com
acturner@traskbritt.com

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal.

None

Dated: May 9, 2018 /s/ *H. Dickson Burton*

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

INTEREST OF *AMICI CURIAE* AND INTRODUCTION

Amici curiae U.S. Inventor, LLC, Norman Abt, PhD, Margaret Betsock, MBA, Deborah Verity, C.P.G., Margaret Blackford, Jairam KP Vanamala, PhD and Sean McGhee, M.D., submit this brief in support of APPELLANT'S COMBINED PETITION FOR PANEL REHEARING OR REHEARING *EN BANC*. No party or party's counsel has authored any portion of this brief, and only Amici and their counsel have funded it.

Amici have no financial interest in the invention at issue in this case. They do have a strong interest, however, in the issues that this case presents because they want small and medium enterprises to be treated fairly by the USPTO.

Pursuant to Federal Rule of Appellate Procedure 29(a) and Federal Circuit Rule 29(c), all parties have consented to its filing.

ARGUMENT

A. The Panel Decision And The Underlying Decision Of The PTAB Do Not Take Into Consideration All The Words, And Therefore All Of The Limitations, Of The Claims.

In contrast to the Board Decision, it is settled that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). The USPTO and the court must thus consider all claim elements when determining patentability of an invention over the prior art; not just those words that the USPTO wants to consider.

In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). As a general matter, the grammar and ordinary meaning of terms as understood by a person having ordinary skill in the art ("PHOSITA") used in a claim will dictate whether, and to what extent, the language limits the claim scope. Even an indefinite claim limitation cannot be disregarded. Compare *In re Wilson*, supra (if no reasonably definite meaning can be ascribed to certain claim language, the claim is indefinite, not obvious).

Here, the Board ignored words of the claims, and therefore an essential limitation. Representative claim 65 reads:

65. A lipid-containing formulation, comprising

a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater,

contained in one or more complementing casings providing controlled delivery of the formulation to a subject,

wherein at least one casing comprises an intermixture of lipids from different sources, and

wherein

(1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

The formulation claimed in claim 65 thus requires a (1) particular "dosage of omega-6 and omega-3 fatty acids" and (2) "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources".

However, as recited and adopted by this Court in the Panel Decision on page 5:

> The Board also found that while "casing" and "dosage" are not expressly defined, the specification states that any "orally accepted form" of delivery is within the scope of the claims. Board Op. at *9. The specification states that "the compositions comprising the lipid formulation disclosed herein may be administered to an individual by any orally accepted form." J.A. 65 ¶34. The Board found that the "casing" and "dosage" terms do not impart patentability to the claimed compositions, and we agree, for the specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations.

This exclusion of the second claim limitation (that of the particular complementing casings) is improper.

To avoid taking the "casings providing controlled delivery of the lipid-containing formulation to a subject" limitation into consideration, the underlying Board Decision's very first Finding of Fact was as follows:

> 1. The Specification teaches that "the lipid formulation disclosed herein may be administered to an individual in any orally accepted form" (Spec. ¶ 34).

Specification ¶ [0034] (Appx65), however, actually states that "[i]n some embodiments, the compositions comprising the lipid formulation disclosed herein may be administered to an individual in any orally accepted form." (US 2009/0264520 A1, underlining added). The first Finding of Fact redacted (*i.e.*, left out) the first three key words of the sentence (*i.e.*, "in some embodiments"; not generally as presented by ¶ [0034] (Appx65), and began its first step of misinterpreting the claims at issue.

Clearly if "in some embodiments", a situation applies, then in other embodiments, it does not. For example, two sentences further in ¶ [0034] it is stated: "In some embodiments, they may be contained in any one or more of but not limited to, a single dosage or sustained and controlled release capsule . . ." (Compare claim 65, "[] one or more complementing casings providing controlled delivery of the formulation to a subject []").

Going further, and leveraging its first "Finding of Fact," the Board Decision went on to state "The Specification does not provide a definition of the term 'casing,' expressly stating that any 'orally accepted form' falls within the scope of the invention (FF 1)." (PTAB Opinion at 9; underlining added). Again, in contrast to the Board Decision, the Specification never "expressly stated that any 'orally accepted form' falls within the scope of the invention." Instead, it merely said "[i]n some embodiments, the compositions comprising the lipid formulation disclosed

herein may be administered to an individual in any orally accepted form." Specification ¶ [0034], Appx65.[1]

Furthermore, and in contrast to the Board's finding (which was unfortunately adopted by the Panel), the specification actually provides that, "It is intended that the following claims define the scope of the disclosure and that methods and structures within the Scope of these claims and their equivalents be covered thereby." (Specification ¶ [0106], Appx97, underlining added). As can be seen, Specification ¶ [0034] does not actually support the assertion that "the specification states that these claim elements are not limiting"; according to the specification, the invention's scope is to be determined by the claims.

"[W]hile appellate courts must respect agency expertise, the [Supreme] Court has 'stressed the importance of not simply rubber-stamping agency fact finding.'" *Dickinson v. Zurko*, 527 U.S. 150, 162-63, 50 USPQ2d 1930, 1936 (1999) (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477-78 (1951)). Rubber-stamping the Board should not happen here. The Board's "fact finding" here is overreaching at best, and its decision should not be rubberstamped to the detriment of a *pro se* applicant.

[1] Similarly, in a point made repeatedly by Applicant and which is supported by the record, neither the Specification nor the claims support a finding that the term "dosage" is not limiting.

Accordingly, the words of, e.g., claim 65 must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). Applying this principle, the second claim element, *i.e.*, "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources" means what it says, which is not inconsistent with the specification, and which must be included in making a patentability determination. Further, this interpretation was asserted by the Applicant during prosecution.

The approach utilized by the Panel and the Board also does not take into consideration the fact that the '034 patent application was filed on April 17, 2009; years before the decisions of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). These decisions were a sea change for patent applicants with respect to claim language under 35 U.S.C. § 101 and patent claims oftentimes needed to be amended to address the sea change, particularly in those applications that were already pending when these decisions went into effect. These significant changes notwithstanding, the claims as written are sufficient under § 101.

B. Taking Into Consideration All The Words Of The Claims, The Claims Are Not Anticipated

None of the Examiner, the Board, or the Panel even really assert that the prior art relied upon in making the anticipation rejections actually expressly or inherently discloses the second claim element, *i.e.*, "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources". Only by ignoring the second element can they get there. Accordingly, since the burden is on the USPTO in that regard, the claims have not been shown to be anticipated under 35 U.S.C. § 102, and the Board Decision should be reconsidered and reversed.

C. The *En Banc* Court Should Clarify That a Claimed Invention Must Be Analyzed as a Whole to Determine Its Patent Eligibility

The Supreme Court has described a two-step test to determine claimed inventions' patent eligibility. First, the claims are reviewed to determine if they are directed to one of the three categories of patent-ineligible subject matter: laws of nature, natural phenomena, and abstract ideas. *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1296-97 (2012). If so, the claims are then further reviewed to determine whether they contain an additional, inventive concept sufficient to

transform them into a patent-eligible application of the ineligible subject matter. *Alice*, 134 S. Ct. at 2355; *Mayo*, 132 S. Ct. at 1296-97.

Consistent with taking all of the words in a claim into consideration, claims must be analyzed as a whole in order to determine their patent eligibility. *Diamond v. Diehr*, 450 U.S. 175, 188, 101 S. Ct. 1048, 1058 (1981); *Parker v. Flook*, 437 U.S. 584, 594 (1978). In *Mayo*, the Court reiterated the importance of considering claims as a whole as part of the eligibility analysis. 132 S. Ct. at 1298 (analyzing all the steps of a claimed method "as an ordered combination" when evaluating eligibility); *see also Alice*, 134 S. Ct. at 2355 n.3 ("Because the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims 'must be considered as a whole.'" (quoting *Diehr*, 450 U.S. at 188, 101 S. Ct. at 1057-58)).

Considering the "claims as a whole", the analysis of the Board Decision again fails. Nature does not provide humanity with the second claim element, *i.e.*, "one or more complementing casings providing controlled delivery of the [lipid-containing] formulation to a subject", "wherein at least one [complementing] casing comprises an intermixture of lipids from different sources". Such a casing is made by the "hand of man", and should thus be found patentable. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Accordingly, the 35 U.S.C. § 101 rejection should also fail.

D. Conclusion

For the above reasons, the Amici respectfully submit that the Court should grant the petition for rehearing and/or rehearing *en banc*.

Dated: May 9, 2018

Respectfully submitted,

/s/ *H. Dickson Burton*

H. Dickson Burton
Allen C. Turner
TRASKBRITT, P.C.
230 South 500 East, Suite 300
Post Office Box 2550
Salt Lake City, UT 84110
Telephone: (801) 532-1922
hdburton@traskbritt.com
acturner@traskbritt.com

Attorneys for Amici

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 9th day of May, 2017, I caused this Brief of *Amici Curiae*, in Support of Appellant's Combined Petition for Rehearing or Rehearing *En Banc* to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users and by email to the pro se appellant.

I further certify that the required number of copies will be hand filed at the Office of the Clerk, United States Court of Appeals for the Federal Circuit in accordance with the Federal Circuit Rules.

/s/ H. Dickson Burton
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

1. This brief complies with the 2,600 word type-volume limits of Fed. Cir. R. 35(g) because, excluding the parts of the document exempted by Fed. R. App. R. 32(f) (cover page, disclosure statement, table of contents, table of citations, statement regarding oral argument, signature block, certificates of counsel, addendum, attachments):

   [X] this brief contains [*1,870*] words.

   [ ] this brief uses a monospaced type and contains [*state the number of*] lines of text.

2. This brief document complies with the typeface and type style requirements because:

   [X] this brief has been prepared in a proportionally spaced typeface using [*Microsoft Word 2016*] in [*14pt Times New Roman*]; *or*

   [ ] this brief has been prepared in a monospaced typeface using [*state name and version of word processing program*] with [*state number of characters per inch and name of type style*].

Dated: May 9, 2018

/s/ H. Dickson Burton
Counsel for Amici Curiae