THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 120

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MARIANO BARBACID and VEERASWAMY MANNE
Junior Party[1]

v.

MICHAEL S. BROWN, JOSEPH L. GOLDSTEIN
and YUVAL REISS
Senior Party[2]

Interference No. 103,586

Heard: May 11, 2000

FINAL DECISION

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[1] Application 07/520,570 filed May 8, 1990, now U.S. Patent No. 5,185,248 issued February 9, 1993. Assigned to E. R. Squibb and Sons, Inc., a Corporation of Delaware.

[2] Application 07/937,893 filed December 22, 1992. Accorded benefit of Application 07/615,715 filed November 20, 1990, now U.S. Patent No. 5,141,851 issued August 25, 1992; and Application 07/510,706 filed April 18, 1990. Assigned to the Board of Regents, University of Texas System.

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Before DOWNEY, WILLIAM F. SMITH and LORIN, Administrative Patent Judges.

DOWNEY, Administrative Patent Judge.

This interference involves a patent to Barbacid et al. (Barbacid), U.S. Patent No. 5,185,248, assigned to E.R. Squibb and Sons, Inc., (a subsidiary of Bristol-Myers Squibb Co.) (hereinafter Squibb), and an application to Brown et al.(Brown), Serial No. 07/937,893, assigned to Board of Regents, University of Texas System, with Genentech, Inc., as non-exclusive licensee of the subject matter of this application.

The subject matter at issue is an assay for identifying a candidate/test substance having the ability to inhibit a farnesyl transferase enzyme. The subject matter at issue is defined by a single count, which count is a bifurcated count which includes Barbacid's patent claim 1 and Brown's claim 37. The count reads as follows:

Count 1

A method for identifying a candidate substance having the ability to inhibit a farnesyl transferase enzyme, comprising the steps of:

(a) obtaining an enzyme composition comprising a farnesyl transferase enzyme that is capable of transferring a farnesyl moiety to a farnesyl acceptor substance;

(b) admixing a candidate substance with the enzyme composition and farnesyl pyrophosphate; and

(c) determining the ability of the farnesyl transferase enzyme to transfer a farnesyl moiety to a farnesyl acceptor substrate in the presence of the candidate substance and in the absence of the candidate substance

OR

An assay for identifying compounds that inhibit ras oncogene activity, comprising:

(a) reacting a protein or peptide substrate having a CAAX motif with farnesyl pyrophosphate and farnesyl-protein transferase in the presence of a test substance, and

(b) detecting whether the farnesyl residue is incorporated into the protein or peptide substrate, in which the ability of the test substance to inhibit ras oncogene activity is indicated by a decrease in the incorporation of the farnesyl residue into the protein or peptide substrate as compared to the amount of the farnesyl residue incorporated into the protein or peptide substrate in the absence of the test substance.

Barbacid claims 1-19 and Brown claims 37, 39, 41, 42, 53, 54, 57, 58 and 60 correspond to the count.

During the preliminary motion stage of this proceeding, Barbacid filed a motion for judgment (Barbacid Motion No. 1) against Brown on the grounds that the Brown claims are unpatentable under 35 U.S.C. § 135(b), which motion was denied. Brown filed a motion for judgment (Brown Motion No. 1) against Barbacid that Barbacid claims are unpatentable under 35 U.S.C. § 112, first paragraph for lack of best mode, which motion was denied. Lastly, Brown filed motion No. 5 pursuant to 37 C.F.R. § 1.633(c)(2) to amend claims 37, 39 and 54 and to add claims 57-60 and Motion No. 6 pursuant to 37 C.F.R. § 1.633(c)(3) to designate Barbacid claims 7, 14, and 17-19 as corresponding to the count. Brown motion 6 was granted, and Brown Motion 5 was granted-in-part to add claims 57-58 and 60 to the Brown application and designate them as corresponding to the

count and denied with respect to the other requests.

No question of interference-in-fact or separate patentability has been raised.

Both parties filed briefs and appeared through counsel at final hearing. The Barbacid record[3] consists of the declarations of coinventors: Drs. Manne and Barbacid and corroborators: Drs. Fernandes, Kumar, Tobia, and Meyers; Messrs. Roberts and Egli; and Misses Long and Cannon accompanied by exhibits 1-49. The Brown record consists of the declarations of coinventors Drs. Brown, Goldstein, and Reiss and corroborators, Dr. Casey and Mr. Falck and Misses McMurray, Chapman, Pokladnik, and Morgan, accompanied by exhibits 1-46.

Brown are senior party, having been accorded benefit of the April 18, 1990 filing date of their earlier filed U.S. application, Serial No. 07/510,706.

The issues presented for our consideration are as follows:

1. Has junior party Barbacid established an actual reduction to practice of the subject matter of the count before senior party's April 18, 1990 effective filing date?;

2. If the answer to 1., is yes, then has senior party Brown established an earlier reduction to practice of the subject matter of the count?;

3. If the answer to 2., is no, then was Brown the first to conceive and last to reduce

[3] The Barbacid record and exhibits will be referred to as BR and BX followed by the appropriate page/exhibit number. In a similar manner, Brown's record and exhibits will be referred to as AR and AX.

to practice accompanied by reasonable diligence prior to the entry of Barbacid into the field?;

4. Brown's motion for judgment (Brown's motion 1) filed pursuant to 35 U.S.C. § 112, first paragraph that Barbacid claims corresponding to the count are unpatentable for failure to disclose the best mode; and

5. Barbacid's motion for judgment (Barbacid's motion 1) filed pursuant to 35 U.S.C. § 135(b)?

6. Brown motion to suppress (Paper No. 109) Opposition (Paper No. 103)

II.

Preliminarily, we note that Barbacid filed a notice pursuant to 37 C.F.R. § 1.640(b) requesting review of the APJ's granting Brown et al. motions 5(in-part) and 6. However, Barbacid do not seek review of these motions in their brief. Matters not raised in the brief are ordinarily regarded as abandoned. Photis v. Lunkenheimer, 225 USPQ 948 (Bd. Pat. Int. 1984).

III.

THE PARTIES BRIEFS

It is not the burden of the Board to scour the record, research any legal theory that comes to mind and serve generally as an advocate for a party. Compare Ernst Haas Studio Inc. v. Palm Press, Inc., 164 F3d 110, 112, 49 USPQ2d 1377, 1379 (CA 2 1999).

Accordingly, in making our determination as to priority we have reviewed only those

specific facts and arguments of the parties relied upon in their briefs. See 37 C.F.R. § 1.656(b)(5) and (b)(6)[4].

Reduction to practice

The issue of reduction to practice is a question of law. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). To establish a reduction to practice of a method count, a party must show that each step of the method was performed. Szekely v. Metcalf, 455 F.2d 1393, 1396, 173 USPQ 116, 119 (CCPA 1972). All limitations of the count have to be satisfied. Id. Such performance may be made by the inventor or someone on his behalf. When reviewing the sufficiency of evidence for reduction to practice a "reasonableness" standard is applied. Holmwood v. Sugavanam, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991).

The reduction to practice must be corroborated in point of time. An inventor must provide independent corroborating evidence in addition to his own statements and documents. Hahn v. Wong, 892 F.2d 1028, 1032, 13 USPQ2d 1313, 1317 (Fed. Cir.

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[4] 37 CFR § 1.656(b)(5) requires:

> [A] statement of facts, in numbered paragraphs, relevant to the issues presented for decision with appropriate references to the record.

and 37 C.F.R. § 1.656(b)(6) requires:

> [A]n argument, which may be preceded by a summary, which shall contain the contentions of the party with respect to the issues to be decided, and the reasons therefor, with citations to the cases, statutes, other authorities, and part of the record relied on.

1989); Lacotte v. Thomas, 758 F.2d 611, 613, 225 USPQ 633, 634 (Fed. Cir. 1985). Such evidence "may consist of testimony of a witness, other than an inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of the information received from the inventor"(our emphasis). Hahn, 892 F.2d at 1032-1033, 13 USPQ at 1317; Reese v. Hurst, 661 F.2d 1222, 1225, 211 USPQ2d 936, 940 (CCPA 1981). The purpose of the rule requiring corroboration is to prevent fraud. Berry v. Webb, 412 F.2d 261, 267, 162 USPQ 170, 174 (CCPA 1969). A rule of reason applies to determine whether the inventor's testimony has been sufficiently corroborated. Price v. Symsek,, 988 F.2d 1187, 1194-1195, 26 USPQ2d 1031, 1036-37 (Fed. Cir. 1993). The "rule of reason" involves an examination, analysis and evaluation of the record as a whole to the end that a reasoned determination as to the credibility of the inventor's story may be reached. Berges v. Gottstein, 618 F.2d 771, 776, 205 USPQ 691, 695 (CCPA 1980); Mann v. Werner, 347 F.2d 636, 642, 146 USPQ 199, 203 (CCPA 1965). There is no single formula that must be followed in proving corroboration. Whether an actual reduction to practice has been corroborated must be decided on the facts of each particular case. Berges, 618 F.2d at 776, 205 USPQ at 695. Nonetheless, adoption of the "rule of reason" has not dispensed with the requirement that corroborative evidence must not depend solely from the inventor himself but must be independent of information received from the inventor. Coleman v. Dines, 754 F.2d 353, 360, 224 USPQ 857, 862 (Fed. Cir. 1985) Reese, 661 F.2d at 1225, 211 USPQ at 940 (CCPA 1981); Mikus v.

Wachtel, 504 F.2d 1150, 1152, 191 USPQ 571, 573 (CCPA 1976). If the process is carried out by the inventors, there must be corroborated evidence that all the limitations as to materials, properties, steps and results required by the count were present in the work performed. Land v. Regan, 342 F.2d 92, 94, 144 USPQ 661, 664 (CCPA 1965); Vandenberg v. Reynolds, 268 F.2d 744, 747, 122 USPQ 381, 383 (CCPA 1959).

Barbacid's Case for Priority (Issue 1)

Since the Barbacid application was copending with the Brown application, Barbacid, as junior party, have the burden to establish priority of invention by a preponderance of the evidence. Bosies v. Benedict, 27 F.3d 539, 541, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994); Peeler v. Miller, 535 F.2d 647, 190 USPQ 117 (CCPA 1976) See also 37 C.F.R. § 1.657(b)[1995].[5].

For an actual reduction to practice of the subject matter of the count, Barbacid rely upon the activities of both Manne, a coinventor, and of Donald Roberts (Roberts), a research associate at Squibb, who worked under the supervision of Manne.

We will focus on the work done by Roberts in March 1990, whose work was performed on behalf of the inventors and was not challenged by Brown in their brief. In fact, at final hearing, counsel for Brown agreed that it would appear that Brown had an

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[5] 37 C.F.R. § 1.657(b), as now amended, states that: [I]n an interference involving copending applications or involving a patent and an application having an effective filing date on or before the date the patent issued, a junior party shall have the burden of establishing priority by a preponderance of the evidence.

actual reduction to practice on March 6, 1990 based on the Roberts' work.

Roberts testified that on March 6, 1990, he screened potential farnesyl inhibitors in an assay. Roberts stated that he tested the inhibition of the farnesyl transferase activity of porcine brain S-100 fraction on p21N aqueous sample in the presence of add SQ 34,183; SQ Ras 1-14 peptide; SQ 34,868; and SQ 34,542 (a 13-mer peptide) in reactions containing and [^{3}H]FPP. (Exhibit 26, page 57). Roberts found that SQ 34,813 and SQ Ras1-14 were >90% inhibitory to porcine brain S-100 farnesyl transferase activity and that SQ 34,542 was inhibitory at . 1mg/ml. (Barbacid record, page 113-114, ¶ 20).

Opinion on Barbacid's Actual Reduction to Practice

We hold, based on the record before us, that Barbacid have proven, by a preponderance of the evidence, an actual reduction to practice of the count no later than March 6, 1990 when SQ 34,813, SQ Ras 1-14 peptide and SQ 34,542 were found to have farnesyl transferase inhibitor activity in the assay performed by Roberts.

IV.

Brown's case for reduction to practice (Issue 2)

For reduction to practice, Brown rely upon the work done September, 11, 20 and 25, 1989 by coinventor Dr. Reiss (Reiss) (See Brown's brief, pp. 31-32, (ii) Reduction to practice), his laboratory notes (Exhibit 32, pages 18, 28-31 and 35-39) and for corroboration, the testimony of Casey (AR, 19-20) to confirm farnesyl transferase (FT) activity in the assay performed September 20 and the results of the experiment allegedly

performed by Reiss on September 25, 1989.

The following paragraphs comprise the complete testimony of Reiss with respect to his activities on the above dates.

13. On September 11, 1989, I conducted another filter assay, this time using membrane fractions from the previous rat brain preparation (Ex 32; page 0018). Though the results were inconclusive, there appeared to be some transfer of radioactively labeled FPP to ras. By this point, we had begun to realize that background radioactivity from ^{14}C-FPP, in this type of study, was going to be a problem and that we needed to lower the background in order to observe any difference between the amount of radioactivity in a labeled *versus* unlabeled ras substrate. (AR -48)

21. On September 20, 1989, I performed yet another assay using whole cell extracts and supernatants from the rat brain preparation of September 18,(Exhibit 32; pages 0028 to 0031). The format of this assay was different in that it did not employ a filter. The rat brain extract supernatant, recombinant ras, reaction mixture (1 M Tris, pH 7.5; 2M KCL; 0.25 M $MgCl_2$; 0.1 M DTT; 0.1 M ATP; 1 mg/ml PK) and ^{14}C-labeled FPP were mixed together and incubated for various times. The samples where then separated by gel electrophoresis. The resulting gel was dried and x-ray film used to detect radiolabeled proteins. As can be seen from the autoradiograph of the gel (Exhibit 32; page 0032), a band migrating between 14.3 and 30 kilodaltons could be observed for several of the reactions including a ras substrate, but not in any lane lacking ras. This clearly indicated a ras-specific reaction in which a molecule, in the approximate molecular size range ras, incorporated ^{14}C-FPP. This was the first study actually demonstrating farnesyl transferase activity *in vitro*. (AR 50-51)

24. On September 25, 1989, I conducted an assay to determine the pH dependence of the farnesyl transferase preparation currently under use (Exhibit 32; pages 0035 to 0039). This study also employed a peptide considered to be a potential inhibitor of ras farnesylation. This peptide comprised the carboxy-terminal ten amino acids of the ras molecule. The format of this assay was the gel electrophoresis format, described above in paragraph 20[sic]. The autoradiograph developed from the corresponding gel (Exhibit 32; page 0038) clearly shows that inclusion of peptide at 10

and 20 Fg (lanes 14 and 15, respectively) inhibited farnesyl transferase-mediated labeling of ras by ^{14}C-FPP, as determined by the reduction/absence of ras-specific bands in these

lanes. (AR 51-52)

Exhibit 32 is identified by Reiss as copies of pages from the first volume of his laboratory notes of studies said to be carried out from August, 1989 into early October of 1989 relating to the farnesyl transferase project (AX-43, ¶ 3). .

Casey, at the time in question, was a post-doctoral fellow in the laboratory of Dr. Alfred Gilman, in the Department of Pharmacology at the University of Texas, Southwestern Medical Center in Dallas, TX. Casey testified that he recalled within a week or so of September 14, 1989, that "Reiss showed me the results of a study in which he had demonstrated farnesyl transferase activity in a gel-based assay." (AR-19, ¶ 8) Casey also testified that "the notebook page 31 shown in Exhibit 32 as page 031 is the experiment Reiss showed to me". With respect to Reiss's work in the latter part of September, 1989, Casey testified that he recalled, "that by at least about the end of October or the beginning of November, I was aware that Dr. Reiss had demonstrated that short peptides, derived from ras, inhibited farnesyl transferase activity *in vitro* in the gel-based assay..." AR-20 ¶ 9)

<u>Opinion re Brown's case for priority</u>

For an actual reduction to practice of the subject matter of the count, the same burden, a preponderance of the evidence, is applied to the senior party, whose application was copending, with respect to providing a date of invention prior to their filing date. <u>Fisher v. Gardiner</u>, 215 USPQ 620 (Bd. Pat. Int. 1981).

We hold, based on the record before us, that Brown have not proved, by a preponderance of evidence, an actual reduction to practice of the subject matter of the count prior to March 6, 1990.

With respect to Reiss's activities of September 11 and 20, 1989[6], Brown argue that if the Board finds that an inhibitor substance need not be added to the process, then the work of Reiss, satisfies the limitations of the count. The Board does not so find. The count clearly requires that a test/candidate substance be included in the assay in order to identify whether the substance serves as an inhibitor of farnesyl activity. To constitute an actual reduction to practice, it must be shown that an experiment satisfies all the limitations of the count in issue. Szekely, 455 F.2d at 1396, 173 USPQ at 119; Schur v. Muller, 372 F.2d 546, 550, 152 USPQ 605, 609 (CCPA 1967). Therefore in order for Brown to prove priority based upon an actual reduction to practice of the process count, Brown must prove by a preponderance of the evidence that the performed experiment carried out each step of the process. Brown made no attempt to do this. With respect to Reiss's activities of September 25, 1989, Brown, in their brief (page 32), argue that the assay Reiss performed on this date incorporated a purified ras (5Fg/ml) as the substrate, ^{14}C-FPP(2000pmol/tube) as the farnesyl pyrophosphate, purified FT in supernatant fraction

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[6]Barbacid correctly notes that Brown's preliminary statement alleges the earliest date of September 25, 1989 for reduction to practice. Accordingly, the earliest date that Brown could possibly establish for an actual reduction to practice is September 25, 1989. See 37 C.F.R. § 1.629(a).

(100Fg/tube) of rat brain cell extracts as the farnesyl transferase enzyme and ras C-terminal lys-0-met peptide at 10Fg or 20Fg as the candidate or test substance.[7] Thus, Brown argue that this experiment performed by Reiss satisfies each of the elements of the count.

Brown also offer Exhibit 32, pages 0035-0039, in support of Reiss's testimony (see supra, ¶¶ 13,21 and 24). Barbacid allege that this document is not authenticated. We agree.

Authentication is defined as "genuineness" and is said to be established, when it is proved to be the thing it is supposed or represented to be. 3 Rivise & Caesar, Interference Law and Practice, § 435, page 1891 (Michie Co. 1943). An exhibit may be authenticated by oral testimony of a witness but not by the uncorroborated testimony

of the party on whose behalf it is offered in evidence. Hence, a witness must properly

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[7] Interestingly, a review of the Reiss testimony indicates that he employed a peptide that comprised the carboxy-terminal ten amino acids of the ras molecule and also recombinant ras (AR ¶ ¶21 and 24). Reiss made no statements that he employed a ras C-terminal lys-0-met peptide or a purified ras, as now alleged by counsel in the Brown brief. Further, a review of the Reiss testimony will also show that Reiss did not identify the concentrations of the components, except for the peptide at 10Fg and 20Fg. Hence, these arguments are unsupported attorney arguments. Meitzner v. Mindick, 549 F.2d 775, 193 USPQ2d 17 (CCPA), cert. denied, 434 U.S. 854 (1977). Exhibits do not speak for themselves. Amoss v. McKinley, 195 USPQ 452, 453-454 (Bd. Pat. Int. 1977). A witness is required to explain the exhibits. 37 C.F.R. § 1.671(f).

identify the exhibit[8] as to what it is as well as to explain the witness's relationship to the document in question. In addition, authenticity of an exhibit must be established both as to subject matter (content) and time. 4 Rivise & Caesar at § 563, page 2418. Documents do not speak for themselves.[9] They must be explained even if they contain a label and a date. Further, 37 C.F.R. § 1.671(f)[10] requires a witness to explain the entries on the

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[8] Extrinsic evidence of authenticity as a condition precedent to admissibility is not required for self-authenticating evidence. See FRE 902.

[9] Amoss v. McKinley, 195 USPQ at 453-454. The extent to which an exhibit is explained depends on the simplicity or complexity of the subject matter as well as technical background of tribunal hearing the case. 3 Rivise, at § 435, page 1891. Herein, because of the complexity and the terminology used in the biotechnical arena, it is most imperative that a witness's explanation as to authorship and content of a document be sufficiently clear and detailed as to the specific entries in the exhibits relied upon by a witness. It is not sufficient to provide a bare allegation that certain work was done citing certain pages of notes or notebooks attached to the affidavit or declaration. It is not the burden of the Board to try to read the exhibits and to correlate allegations made in the testimony with specific entries. Amoss, citing Gipstein v. Contois, 191 USPQ 688, 690 (Bd. Pat. Int. 1975); and Golota v. Strom, 489 F.2d 1287, 1292-1293, 180 USPQ 396, 400-401 (Bd. Pat. Int. 1975); Triplett v. Steinmayer, 129 F.2d 869, 871-872, 54 USPQ 409, 411-412 (CCPA 1942); Chandler v. Mock, 150 F.2d 563, 567-568, 66 USPQ 209, 213-214 (CCPA 1945); Teel v. Cotton, 151 USPQ 428, 430-431 (Bd. Pat. Int. 1966); Popoff v. Orchin, 144 USPQ 762, 763 (Bd. Pat. Int. 1963); and In re Borkowski, 505 F.2d 713, 194 USPQ 29 (CCPA 1974).

[10] C.F.R. § 1.671(f) states that "[T[he significance of documentary and other exhibits shall be discussed with particularity by a witness during oral deposition or in an affidavit." See Patent Interference Proceedings: Final Rule, 49 F.R. 48416, 48447, col. 3, 1050 Off. Gaz. Pat. Office 385, 416. In 1984 the rules were amended to require the particularized explanation of material in non-self authenticating documents. The commentary explained that "[B]y providing in the rules that documentary evidence must be explained, the PTO hopes to save both parties and the Board considerable difficulty in presenting and evaluating evidence."

various pages of the notebooks/exhibits. This explanation provides the opponent party and the Board a basis to determine whether the witness' testimony is supported by contemporaneous documentation or whether a party is relying upon the witness's oral testimony.

While, Reiss himself indicates that exhibit 32 is a copy of his laboratory notes from August 89 into early October 89[11], he provides no testimony regarding the specific entries on the exhibit and how such entries support his testimony. Our review of exhibit 32, pages 35-39, shows that it consists of a series of unnumbered loose pages that are unsigned and unwitnessed. The pages(35, 36, 38 and 39) are handwritten[12] and contain abbreviations and acronyms. Loose-leaf pages 38-39 appear to contain autoradiograms. Some pages(35, 38-39) bear a date of September 25, 1989, another (page 37) 9/26 and another (page 36) undated. While pages 38-39 bear a date of 9/25/89; they also refer to either "expo: 2 days" or "expo: 3 days" which terms were not explained. In view of the fact that Reiss failed to adequately explain Exhibit 32 as to its content and time and to explain in detail how specific entries on the document support his testimony, we find the exhibit unauthenticated and of little probative value.

Even if were to assume that this exhibit were adequately explained by Reiss, it

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[11] Notes and notebooks are not self-authenticating. FRE 902.

[12] Where a party submits a handwritten exhibit, a typed copy of the document should be provided on a separate piece of paper and attached to the exhibit. Cf. Latimer v. Wetmore, 231 USPQ 131 (Bd. Pat. App. & Int. 1985)

would not be sufficient, along with Reiss's testimony to establish an actual reduction to practice. An inventor's testimony and documentation are self serving and cannot be corroborative of the inventor's work. Hahn, 892 F.2d at 1031, 13 USPQ2d at 1215.

Brown offers the testimony of Casey to corroborate Reiss's work. We find Casey's testimony insufficient to establish an actual reduction to practice by Reiss. As noted earlier, Casey, with respect to the alleged experiment of September 25, 1989 testified that "he recalled that by at least about the end of October or the beginning of November, I was aware that Dr. Reiss had demonstrated that short peptides, derived from ras, inhibited farnesyl transferase activity *in vitro* in the gel-based assay ...". Even in the most favorable light, this testimony is not sufficient to establish an actual reduction to practice by Brown.

As correctly pointed out by Barbacid, it is necessary that corroboration be independent of the inventor. The record does not establish that Casey had first-hand knowledge of the alleged experiment carried out by Reiss or of the results of such experiment. His testimony that upon recall he was aware of what Reiss had demonstrated that short peptides inhibit FT activity does not establish that the method of the count was successfully performed. On this record, Casey does not explain how he became aware. He could have become aware of this information from the inventor. The burden is on Brown to prove that information was not derived from the inventor but rather independent of the inventor. Zoiss v. Nix, 185 USPQ 419 (Bd. Pat. App. & Interference 1974). While the rule of reason has eased the requirement of corroboration with respect to the quantum of

evidence necessary to establish the inventor's credibility, it has not altered the requirement that corroborative evidence must not depend solely on the inventor himself and must be independent of information received from the inventor. White v. Haberstein, 219 USPQ 1213, 1217 (Bd. Pat. App. & Int. 1983); citing Reese and Mikus [citations omitted]. Moreover, Casey's broad statements are not sufficiently specific to support a holding that Brown has established a reduction to practice. Corroboration must consist of factual evidence as to what was done, not of broad generalizations or conclusions. Murphy v. Eiseman, 166 USPQ 149 (Bd. Pat. App. & Int. 1970) ; Azar v. Burns, 188 USPQ 601 (Bd. Pat. App. & Int. 1975).

Thus after a reasoned examination, analysis and evaluation of all the pertinent evidence relied upon by Brown et al., we find that the work allegedly done by the inventors stands uncorroborated and thus, Brown have not established that they were the first to reduce to practice the subject matter of the count.

V.

Was Brown the first to conceive and last to reduce to practice with the requisite diligence (Issue 3)

Since we have found that Barbacid was the first to reduce the invention to practice, Brown can still prevail if they establish that they were the first to conceive and last to reduce to practice with reasonable diligence from a time prior to conception by another. 35 U.S.C. § 102(g).

Conception is a question of law. Kridl v. McCormick, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689(Fed. Cir. 1997); Bosies v. Benedict, 27 F.3d 539, 542, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994) and Fiers v. Revel, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604 (Fed. Cir. 1993). Conception is defined as the formation "in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech, 802 F.2d at 1376, 231USPQ at 87 (Fed. Cir. 1986). By this definition, conception consists of two parts, the idea and the means to carry out the idea. Conception must include every limitation in the count, and every limitation must have been known to the inventor at the time of the alleged conception. Coleman, 754 F.2d at 359, 224 USPQ at 862. Conception of an inventive process involves proof of mental possession of the steps of an operative process and, if necessary, of means to carry it out to such a degree that nothing remains but routine skill for effectuation thereof. Alpert v. Slatin, 305 F.2d 891, 134 USPQ 296 (CCPA 1962). Since conception takes place in the mind of the inventor, additionally there must be disclosure to and corroboration by a third party. For it is well settled that the inventor's testimony standing alone is insufficient to prove conception, Price, 988 F.2d at 1194, 26 USPQ at 1036. In evaluating whether there is conception, a rule of reason is applied, the rule does not however dispense with the requirement of some evidence of independent corroboration. Coleman, 754 F.2d at 359, 224 USPQ at 862.

For conception, Brown rely upon the statements of coinventor Reiss, and on the

alleged discussions Reiss and other coinventors were said to have had with Casey and the testimony of Falck.[13]

Brown's case for conception can be summarized as follows. Reiss testified that he came to Southwestern on August 1, 1989 where he was to begin a research project with Brown and Goldstein involving the development of an *in vitro* assay for farnesyl transferase activity. He testified that on that day, he met with Brown and Goldstein and discussed the project dealing with the isolation and characterization of the enzyme responsible for the farnesylation of the ras protein. Reiss testified that sometime in the second week of August, 1989, the three coinventors again met to map out a strategy for generating a active farnesyl transferase enzyme preparation and developing an assay for farnesyl transferase activity. (AR 44, ¶ 5) During these discussions, Reiss testified that they discussed the use of ras and ras-related peptides as substrates for the enzyme and farnesyl pyrophosphate as the source of the farnesyl and that Goldstein suggested brain tissue as the source of the enzyme. Reiss testified that by August 21, 1989 he prepared a FT enzyme preparation and on September 20, 1989, the preparation demonstrated FT activity. Reiss also rely upon exhibits Ex 32, page 001, 0017-0018, and 0028-0031.

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[13] Brown, in their brief, refer to activities of Falck in their statement of facts and argument; however, they do not explain how the activities of Falck establish conception by Brown et al. Falck testified that he agreed to provide Goldstein and his colleagues with FPP and farnesylated enzyme. He further testified that he prepared FPP and farnesyl bromide (not S-farnesyl cysteine). There is no testimony by Falck that the agreed upon materials were made and transferred or shipped to Brown.

For corroboration, Brown rely upon the testimony of Casey regarding the August 11th meeting. Casey testified with respect to the August meeting with the coinventors that discussions included identifying farnesyl pyrophosphate as a logical choice for farnesyl in the assay, and using ras and ras-related peptides as substrates for the enzyme[14]. With respect to the September 20, 1989 work of Reiss, Casey testified that within a week or so of September 14, 1989, he recalled that "Dr. Reiss showed me the results of a study in which he had demonstrated farnesyl transferase activity in a gel-based assay."

Opinion re Brown's case of conception

We find that the Brown record does not establish a complete conception of the count. [15]

As to the August 1, 1989 meeting, the testimony offered is that of the inventors. However, there is no testimony regarding the use of a test/candidate substance in the assay. Hence, Brown has not established that these discussions at this meeting satisfy the limitations of the count. Moreover, it is well settled that the inventor's testimony requires corroboration and here, Brown offer none.

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[14] Brown, in their brief(page 29), indicate that Casey discussed various issues such as the source of FT. Casey's testimony refers broadly to discussions of the choice of starting material and does not corroborate Reiss' testimony that Goldstein had suggested brain tissue as the source of FT.

[15] Without a conception, the issue of reasonable diligence by the inventors to a reduction to practice is moot. Accordingly, we have not considered any evidence relating to diligence.

Brown argue (Brief, page 30) that by the middle of August, 1989, the inventors had a clear and definite approach of isolating and testing the subject matter of the count. Such argument is not supported by the evidence of record. Meitzner v. Mindick, 549 F.2d 775, 193 USPQ2d 17 (CCPA), cert. denied, 434 U.S. 854 (1977) (Attorney argument will not take the place of evidence in the record). Reiss's testimony only indicates that by mid August that they had a strategy to obtain a FT enzyme and an assay to determine FT activity. There is no testimony relating to the performance of an assay that included a test substance and the identification of whether the substance serves as an inhibitor of FT activity. Thus, Brown has not established that they were in possession of a complete conception. Conception must include every limitation in the count, and every limitation must have been known to the inventor at the time of the alleged conception.

Nor do we find the alleged work of Reiss on September 20, 1989 to establish a complete conception of the count. As noted earlier, the count requires the presence of a test/candidate substance in the assay. Here, Brown fails to explain how the enzyme preparation and the testing of the enzyme for FT activity establishes a complete conception of the subject matter of the count.

Similarly, Casey's testimony regarding the August 11, 1989 meeting is not sufficient in that it does not establish that the inventors had possession of the subject matter of the count. There is no testimony that the inventor disclosed the subject matter of the count to Casey. At best, Casey establishes use of ras or ras-peptides as substrates

and FPP as the farnesyl source. He does not corroborate Reiss's testimony as to brain tissue as the source of the enzyme. And he does not corroborate the use of a test substance in the screening assay as required by the count. Lastly, Casey's testimony that a coinventor showed him the results of a study are not sufficiently explanatory to establish that the inventors were in possession of the subject matter of the count. In each instance, the testimony offered by Brown relates to finding the enzyme which serves to transfer the farnesyl to the ras substrate but does not relate to the use of test substance in an assay containing FT enzyme, a farnesyl acceptor substance or a protein or peptide substrate having a CAAX motif, and FPP to determine whether the test substance serves as an inhibitor for FT activity.

VI.

Barbacid motion (Issue 5)

Since we find that Brown does not have a corroborated conception, Brown cannot prevail. Barbacid prevails based by being the first to reduce to practice the subject matter of the count. Since Barbacid will be awarded priority, the Board does not find it necessary to direct attention to the Barbacid motion that the Brown claims are unpatentable under 35 U.S.C. § 135(b). However, the Board will address the Brown motion against Barbacid for unpatentablility.

VII.

Brown motion (Issue 4)

Brown filed a motion for judgment (Brown Motion 1) against Barbacid on the grounds that the Barbacid patent claims are unpatentable under 35 U.S.C. § 112, first paragraph for violation of the best mode.

Brown, as movant, bears the burden of proof as to the relief requested. Kubota v. Shibuya, 999 F.2d 517, 520, 27 USPQ2d 1418, 1420 (Fed. Cir. 1993) and 37 C.F.R. § 1.637(a). The burden of proof on a preliminary motion is preponderance of the evidence. See Kubota, 999 F.2d at 519 n. 2, 27 USPQ2d at 1420, n. 2 and Schrag v. Strosser, 21 USPQ2d 1025, 1027 (Bd. Pat. App. & Int. 1991)

We, as a panel, have carefully reviewed the Brown motion and the arguments therein, and we find that Brown have not sustained their burden of proof to establish that the Barbacid claims are in violation of the best mode. 35 U.S.C. § 112, first paragraph.[16]

The first paragraph of 35 U.S.C. § 112 provides, in relevant part, that the specification "shall set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C. § 112.

Best mode is a question of fact. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535-1536, 3 USPQ2d 1737, 1745 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987). The purpose of the best mode requirement is to ensure that the public, in exchange for the

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[16] 37 C.F.R. § 1.655 was amended to emphasize that a panel of the Board will resolve the merits of an interference as a panel without deference to any interlocutory order. The abuse of discretion standard applies only to interlocutory procedural orders. See Consideration of Interference Rulings at Final Hearing in Interference Proceedings. F.R. Vol 64, No. 50 (March 16, 1999) pp. 12900-12902.

rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention which they conceived. Id. See also In re Gay, 309 F.2d 769, 135 USPQ 311 (CCPA 1962).

Determining whether a patent complies with the best mode requirement involves two underlying factual inquiries. First, it must be determined whether, at the time the patent application was filed, the inventor had a best mode of practicing the claimed invention. Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). Thus, the first inquiry is subjective Chemcast, 913 F.2d at 928, 16 USPQ2d at 1037 and focuses on the inventor's state of mind at the time they filed their application. Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir.), cert. denied, 516 U.S. 988 (1995). Second, if the inventor had a best mode of practicing the claimed invention, it must be determined whether the specification adequately disclosed what the inventor contemplated as the best mode so that those having ordinary skill in the art could practice it. Chemcast, 913 F.2d at 927-928, 16 USPQ 2d at 1036-37. Thus, the second inquiry is objective and depends upon the scope of the claimed invention and the level of the skill in the art. Chemcast, 913 F.2d at 928-929, 16 USPQ2d at 1037.

Brown, in their motion allege that the Barbacid specification is defective in that it fails to identify any particular test substance used in the Barbacid claimed process. Brown contend that Barbacid "were aware of particular test substances that had been successfully tested and shown to have measurable activity in inhibiting farnesyl transferase

activity" in the assay prior to filing their application. Brown arrive at this position after noting that Manne and Barbacid and others authored a manuscript, later published in October, 1990, in vol. 87 of the PNAS, pp. 7541-7545, which identified the use of a specific tetradecapeptide (Tyr-Ser-Gly-Pro-Ser-Met-Ser-Ser-Lys-Cys-Val-Leu-Ser) as a test substance found to block *in vitro* farnesylation of p21N. Brown posits that because a test substance is a recited element in the instant claims, and test substance(s) had to been known, it necessarily follows that Barbacid contemplated at least one of these tested substances as the best inhibitor and Barbacid's failure to disclose "the test substance known to applicant at the time of filing to be the *best* inhibitor" is a violation of the best mode (brief, page 71)

We have carefully reviewed the Brown motion and find that Brown has not established that Barbacid at the time of filing his application, had a preferred embodiment for carrying out his screening assay. On this record, Brown has not established that Barbacid knowingly withheld information regarding the best way to practice the claimed process. Absent evidence of accidental or actual concealment by applicant, a rejection for failure to provide the best mode cannot be sustained. In re Sherwood, 613 F.2d 809, 204 USPQ 537 (CCPA 1980). Hence, we hold that Brown have not sustained their burden of proof.

Initially we note that Brown's argument regarding the use of a tetradecapeptide as a test substance has not been raised by Brown in their brief. Accordingly, that argument is

deemed abandoned. Photis, 225 USPQ at 950.

Brown's initial argument that the Barbacid specification is defective because it failed to disclose any test substance used in the assay is tantamount to arguing that Barbacid disclosed no mode at all. However, failure to set forth any mode is an enablement issue, i.e. how to use an invention. U.S. Department of Energy v. Daugherty, 215 USPQ 4, 11 (CCPA 1982). Enablement and best mode are separate requirements. Engel Industries, Inc. v. The Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991). We decline to entertain Brown's attack of no disclosure as a best mode violation when in fact, no mode is an enablement issue, not previously raised by Brown.

Brown's argument that it is necessary that Barbacid disclose in their specification the test substance found by Barbacid to have the best measurable activity is without merit. The Barbacid claims are directed to a screening assay which examines whether a test substance has the ability to specifically inhibit the transfer of farnesyl to ras. When the assay is performed, the test substance either reduces the level of FT activity or it does not and those that reduce the level of FT activity are identified as inhibitors for FT activity. Barbacid's claims are not directed to a method of determining which inhibitor possesses the greatest reduction in FT activity.

Brown, in their brief, now argue that the evidence taken during the testimony period shows that Barbacid tested and found a peptide corresponding to the C-terminus of ras (a

nonapeptide used by Roberts, BX 26) effective in inhibiting transfer of radiolabeled farnesyl into ras. This argument, however, relies upon evidence said to be adduced during the testimony period. When evidence comes to light which in the opinion of a party would provide basis for a preliminary motion under 37 C.F.R. § 1.633, that party may not simply raise the matter in its brief at final hearing for the Boards consideration. The party is required to file a belated preliminary motion. See Interference Practice: Matters Relating to Belated Preliminary Motions, Chairman's Notice of October 6, 1992 1144 OG 8 (Nov. 3, 1992). Accordingly, this new evidence is not entitled to consideration.

Lastly, we are not persuaded by Brown's argument that a positive control, i.e. a known positive inhibitor, is necessary to confirm the accuracy of the results of the assay. In our view, reproducibility of the process is demonstrated when the performed assay in the absence of a test substance produces a substantially consistent level of FT activity.

VIII.

Brown motion to suppress (Issue 6)

In the motion, Brown move to suppress the Fernandes declaration filed in opposition to the Brown motion 1 and the Manne declaration filed with the Barbacid motion 1. It is Brown's position that these declarations submitted during the preliminary motion stage were not submitted into the record in accordance with the rules. 37 C.F.R. § 1.671(e).

The motion to suppress is deemed moot. Barbacid motion 1 was not considered.

Brown did not sustain their burden of proof in their motion that they were entitled to the relief requested. Hence it was not necessary to address rebuttal evidence filed with the opposition paper.

JUDGMENT

For the foregoing reasons, judgment as to the subject matter of the count is entered in favor of junior party, Mariano Barbacid and Veeraswamy Manne and judgment is awarded against senior party Michael S. Brown, Joseph L. Goldstein and Yuval Reiss.

Interference No. 103,586

Accordingly, Barbacid et al. are entitled to their patent containing claims 1-19 and Brown et al. are not entitled to a patent containing claim 37, 39, 41, 42, 53, 54, and claims 57, 58 and 60 corresponding to the count.

MARY F. DOWNEY)
Administrative Patent Judge)
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WILLIAM F. SMITH Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES))
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