

United States Court of Appeals for the Federal Circuit

05-1119
(Interference No. 103,586)

MICHAEL S. BROWN, JOSEPH L. GOLDSTEIN, and YUVAL REISS,

Appellants,

v.

MARIANO BARBACID and VEERASWAMY MANNE,

Appellees.

David L. Parker, Fulbright & Jaworski, L.L.P., of Austin, Texas, argued for appellants. With him on the brief was Rebecca Edgar Melton. Of counsel was Marcy Hogan Greer.

Madison C. Jellins, Townsend and Townsend and Crew, LLP, of Palo Alto, California, argued for appellees. With her on the brief was Steven W. Parmelee, of San Francisco, California.

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

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DECIDED: February 2, 2006

Before NEWMAN, RADER, and PROST, Circuit Judges.

NEWMAN, Circuit Judge.

This appeal of an invention priority determination, called a patent "interference" proceeding, returns to the Federal Circuit from the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office. The parties are Michael Brown, Joseph Goldstein and Yuval Reiss (together "Brown") and Mariano Barbacid and Veeraswamy Manne (together "Barbacid"). The invention common to Brown

and Barbacid is a method or assay for identifying compounds that inhibit farnesyl transferase ("FT"), an enzyme involved in the control of cell growth. The contested subject matter is stated in the interference count as follows:

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 moiety 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.

The Barbacid filing date is May 8, 1990; the Brown application has an effective filing date of April 18, 1990.

In the first appeal, Brown v. Barbacid, 276 F.3d 1327 (Fed. Cir. 2002) ("Brown I"), this court held that the Board erred in holding, *inter alia*, that the laboratory notebooks and recorded autoradiographs of Dr. Yuval Reiss were inadequately explained on their face and therefore could not serve as evidence of either conception or reduction to practice. The Federal Circuit reversed, holding that the Board must "weigh that evidence from the vantage point of one of skill in the art," Brown I, 276 F.3d at 1334, and that the testimony of

Dr. Patrick Casey, taken with the content of the notebooks, was adequate to corroborate Dr. Reiss' testimony as to conception of the invention, although Dr. Casey's evidence was not sufficiently specific to serve as corroboration of an actual reduction to practice. The court stated that "while Dr. Casey's vague testimony does not corroborate Dr. Reiss' testimony of an actual reduction to practice, Dr. Casey's testimony certainly suggests that Dr. Reiss had the idea of combining the FT assay with the use of FT peptide inhibitors sometime before the end of October or the beginning of November 1989." Brown I, 276 F.3d at 1337. We remanded to the Board for more precise determination of the party Brown's date of conception, and determination of Brown's reasonable diligence, as the party who was first to conceive but second to reduce to practice.

On remand, the Board held that Brown had established conception no later than November 15, 1989, but had failed to provide corroborated evidence of diligence. Barbacid v. Brown, Interf. No. 103,586 (Bd. Pat. App. & Interf. Sept. 28, 2004) ("Brown II"). The Board again awarded priority to Barbacid, and Brown again appeals.

DISCUSSION

The party that is first to conceive the invention in interference, if last to reduce the invention to practice, is entitled to the patent based on prior conception if, as first to conceive, he exercised reasonable diligence from a time before the other party's conception date to his own reduction to practice date. See 35 U.S.C. §102(g) (in determining priority "there shall be considered . . . the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other"); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996) (a party that is

first to conceive but second to reduce to practice "must demonstrate reasonable diligence toward reduction to practice").

The purpose of requiring reasonable diligence by the first to conceive the invention but second to reduce to practice is to assure that the invention was not abandoned or unreasonably delayed by the first inventor during the period after the second inventor entered the field. The question of reasonable diligence is one of fact. In re Jolley, 308 F.3d 1317, 1329 (Fed. Cir. 2002); Scott v. Koyama, 281 F.3d 1243, 1246 (Fed. Cir. 2002). We review the Board's factual findings for support by substantial evidence. See Dickinson v. Zurko, 527 U.S. 150, 155 (1999) (applying the criteria of the Administrative Procedure Act to review of rulings of the Patent and Trademark Office). The admissibility of physical and testimonial evidence is determined in accordance with the Federal Rules of Evidence, which have been adopted by the Board, 37 C.F.R. §1.671(b) (1998), as amplified by precedent directed to patent interference proceedings.¹

¹ The PTO adopted new interference rules, effective September 13, 2004. See 69 Fed. Reg. 49960 (Aug. 12, 2004) (removing §§1.601 through 1.690 and adding 37 C.F.R. §§41.200 through 41.208). The Board acknowledged the change, but did not err in continuing to apply the rules under which this case was decided. See also 37 C.F.R. §41.152(a) (2005) ("Except as otherwise provided in this subpart, the Federal Rules of Evidence shall apply to contested cases.").

Barbacid argues that Brown must show diligence measured from the Barbacid date of conception, not Barbacid's date of reduction to practice. The first Board decision found Barbacid's date of actual reduction to practice; the Board did not decide Barbacid's conception date. Barbacid, the junior party, had been accorded its date of actual reduction to practice of March 6, 1990. No earlier date was proposed to this court in Brown I. Thus this court instructed that on remand the Board should determine whether Brown showed reasonable diligence from March 6, 1990, until Brown's filing date as constructive reduction to practice on April 18, 1990. Barbacid states that the Federal Circuit in Brown I erroneously limited the diligence inquiry to the period starting with Barbacid's date of reduction to practice, rather than the date of Barbacid's conception. See Mahurkar, 79 F.3d at 1578 (when the first to conceive is the last to reduce to practice, reasonable diligence must be shown from "a date just prior to the other party's conception"). Brown responds that this objection was not preserved, for Barbacid's brief in Brown I did not suggest its possible entitlement to an earlier date than the reduction to practice date awarded by the Board. Further, Barbacid filed no objection, such as a request for reconsideration or clarification, if Barbacid believed that this court had issued legally flawed instructions for the determination of diligence on remand to the Board. This court's instruction that the Board should determine Brown's diligence upon remand necessarily presupposed that Barbacid did not have a prior conception date, for diligence is only required for the party that is "first to conceive." 35 U.S.C. §102(g). Brown states that this silence by Barbacid was a waiver of the issue of the scope of the diligence showing. We agree. On the information before the court, and the silence throughout briefing, argument, and decision, we hold that Barbacid waived the issue of the length of the period during which diligence should be

shown. The Board did not err in declining to open the issue on remand. Cf. Barrow v. Falck, 11 F.3d 729, 730 (7th Cir. 1993) ("An argument bypassed by the litigants, and therefore not presented in the court of appeals, may not be resurrected on remand and used as a reason to disregard the court of appeals' decision").

Brown provided evidence from inventor Dr. Reiss and laboratory technician Ms. Morgan concerning the exercise of reasonable diligence during the period from Barbacid's accorded date to Brown's filing date. Dr. Reiss stated that after September 1989 he worked on the farnesyl transferase project "on a daily basis." For the period following Barbacid's actual reduction to practice on March 6, 1990, Dr. Reiss stated that his experiments were directed at further characterizing the FT enzyme, improving the methodology for purifying the enzyme, and improving the overall performance of the assay. He stated that he performed studies to assess the metal dependency of FT, evaluated gels with various affinity chromatography eluates, conducted a freeze-thaw study to determine the stability of FT, performed cyanide bromide cleavage of various FT fractions and examined the products of that cleavage, studied the effect of guanosine triphosphate binding on farnesylation, and studied the effect of peptide saturation on FT activity. He provided laboratory notebook pages recording this work.

The Board rejected Dr. Reiss' testimony for lack of corroboration, and also observed that even if his notebook records showing this work were deemed to corroborate his testimony, they recorded work on only ten of the thirty-one days from March 6 to April 18, and thus were insufficient to establish reasonable diligence.

Precedent requires that an inventor's testimony concerning his diligence be corroborated. See Jolley, 308 F.3d at 1328 ("corroboration is required to support an

inventor's testimony regarding his reasonable diligence in pursuit of the invention"). Corroboration is determined by application of a rule of reason, for "corroboration of every factual issue contested by the parties is not a requirement of law." Jolley, 308 F.3d at 1328; see also Price v. Symsek, 988 F.2d 1187, 1196 (Fed. Cir. 1993) ("all of the evidence put forth" must be considered "as a whole, not individually" in evaluating whether the inventor's testimony is credible).

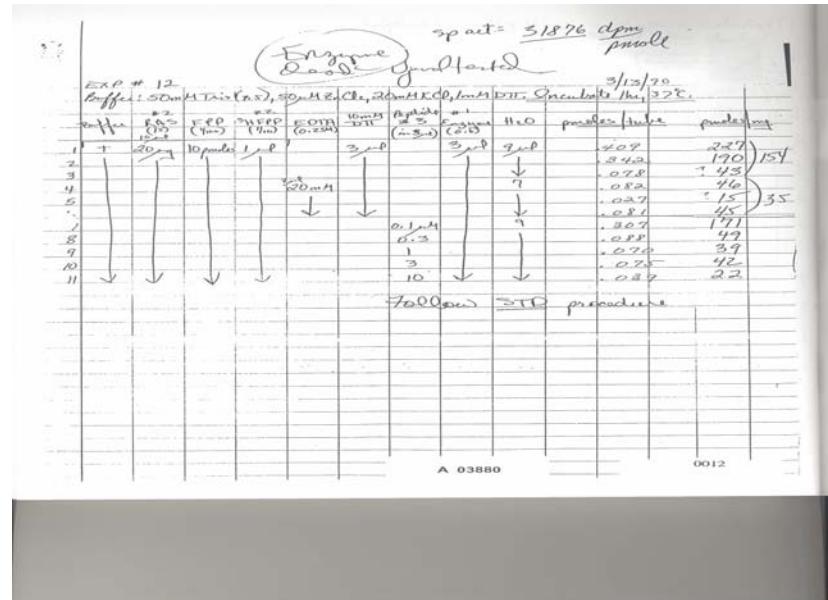
Unlike the legal rigor of conception and reduction to practice, diligence and its corroboration may be shown by a variety of activities, as precedent illustrates. For example, in Lacotte v. Thomas, 758 F.2d 611, 613 (Fed. Cir. 1985), the testimony of the inventor and his notebook records were held adequately corroborated by his obtaining relevant supplies and the testimony of his associate. In Bey v. Kollonitsch, 806 F.2d 1024, 1030 (Fed. Cir. 1986), diligence was shown by an attorney's work in preparing the patent application. In Scott v. Koyama, 281 F.3d at 1248, diligence was shown by efforts to locate a construction company capable of building a manufacturing plant for practicing the process on a large scale. In Jolley, 308 F.3d at 1327, diligence was shown by activity to obtain necessary supplies and laboratory glassware and by testing of related materials. The basic inquiry is whether, on all of the evidence, there was reasonably continuing activity to reduce the invention to practice. There is no rule requiring a specific kind of activity in determining whether the applicant was reasonably diligent in proceeding toward an actual or constructive reduction to practice.

Brown provided evidence of laboratory work during this period performed by Debra Morgan, a scientist working in the Brown laboratory, as evidence of diligence and as corroboration of Dr. Reiss' testimony. Ms. Morgan declared that she was aware that Dr.

Reiss "was working on . . . the development of an assay for screening of potential inhibitors of this [FT] enzyme," that she worked on the FT assay, and that she performed experiments designed by Dr. Reiss. Ms. Morgan stated that her work was to "screen various peptides for possible inhibitory effect on farnesyl transferase." She stated that the studies used a fiber-binding assay format where "farnesyl transferase, ³H-Fpp, ras substrate and the candidate inhibitor peptide were incubated together," and that the methodology of the assay was that "when the radioactively labeled FPP is incorporated into the ras substrate, the radioactivity will associate with the filter by virtue of the adsorption of the ras thereto." Ms. Morgan described various farnesyl transferase inhibition studies with reference to the specific study numbers on the notebook pages, and the dates the work was done. She explained a comparative study, with reference to study number and date, in which "a biotin conjugated substrate is used rather than ras as a target for farnesylation," as well as a study in which farnesyl transferase reaction samples were prepared for analysis by thin layer chromatography. Her declaration was accompanied by copies of thirty-eight laboratory notebook pages. Each of the thirty-eight notebook pages was associated with tests specified in her declaration.

The Board found that Ms. Morgan's notebook records along with those of Dr. Reiss filled all but six days of the critical period, and that each of the six remaining days was a single-day gap; this was deemed sufficient to show substantially continuing activity. The Board found that Ms. Morgan "worked for the inventors" and that "her work could inure to the benefit of the inventors to establish reasonable diligence over the entire period." However, the Board refused to credit any of Ms. Morgan's evidence, criticizing what it described as the absence of explanation of the content and purpose of these experiments.

The Board stated that it was not clear from the face of the notebook pages what Ms. Morgan had done and why, presenting as an example of an inadequate record the following page of Ms. Morgan's notebook:



The Board stated that it "surmised" that this page recorded eleven experiments involving the ras oncogene protein, farnesyl pyrophosphate, and a peptide, based on the designations "RAS," "FPP" and "Peptide #3" in the column headings. The Board described its concerns as follows:

the relationship between ras, farnesyl pyrophosphate and peptide is not explained. Nor are the results of the assays understood. What do they signify? . . . The issue is whether Ms. Morgan's work shows reasonable diligence was exercised to reduce the invention of the count to practice. We are given a number of laboratory pages, the content of which is never explained, leaving it to us to decipher whether they are relevant and to what extent they are relevant to the issue of reasonable diligence. There is no explanation of what these pages are saying.

Bd. op. at 25-26. The Board also stated that if Ms. Morgan's evidence were credited, it would suffice, with that of Dr. Reiss, to establish diligence.

Brown states that Ms. Morgan's work was explained in her declaration, and that her notebook pages report the subject of her studies in scientific detail that would be readily understood by persons experienced in this field. Brown points out that her declaration references specific study numbers recorded on the notebook pages and the dates recorded on those pages, and that her declaration and documentary records would be understood by persons experienced in this field of science. Brown states that the Board erred in requiring that the records themselves and the content of the supporting declaration contain explanations more elaborate than needed to record the work and communicate to persons experienced in this field. Barbacid defends the Board's ruling, characterizing Ms. Morgan's testimony as "cursory" and fatally flawed because it did not explain how each experiment moved the inventive process toward completion, and states that the Board acted reasonably in refusing to credit any of Ms. Morgan's evidence as showing reasonable diligence and establishing corroboration of Dr. Reiss' testimony.

We conclude that the Board erred in law, in failing to view the proffered evidence as it would be viewed by persons experienced in the field of the invention. See Mahurkar, 79 F.3d at 1577-78 (the trier of fact is aided by an understanding of how the evidence would be viewed by one skilled in the art). The Board is charged with expertise appropriate to the invention under examination, and with understanding that a laboratory notebook recording daily experimentation, reasonably considered from the viewpoint of persons experienced in the field, need not reproduce on each page a statement of the larger research purpose; this purpose may reasonably be shown in the various declarations.

It is undisputed that the subject matter recorded on the Morgan notebook pages and described in her declaration concerns the subject matter of the count. This is the same form and content of evidence that the court in Brown I deemed admissible for purposes of showing conception. The Board agreed that Ms. Morgan's activity during the critical period, if accepted into evidence, established diligence. We conclude that the Board erred in refusing to accept this evidence, and that reasonable diligence is deemed established.

The Board's holding that Brown's reasonable diligence had not been shown is reversed. The only remaining issue of which we have been made aware relates to patentability. The Board did not review the ruling of the administrative patent judge denying Barbacid's motion challenging the patentability of Brown's claims, deeming this aspect "moot" because of the award of priority to Barbacid. Brown asks us to take up this issue "in the interests of judicial economy," expressing concern about the time already consumed in this interference proceeding and the delay of a further remand. Indeed, this interference has been pending for over ten years. However, we must agree with Barbacid that the question of patentability cannot be decided *ab initio* on appeal. See In re Lee, 277 F.3d 1338, 1345 (Fed. Cir. 2002) ("review of an administrative decision must be made on the grounds relied on by the agency"). Although we deplore the lengthy pendency of this proceeding, on remand the Board may decide whether further proceedings as to this issue are warranted.

REVERSED and REMANDED