United States Court of Appeals for the Federal Circuit

2009-1258

VANDERBILT UNIVERSITY,

Plaintiff-Appellant,

v.

ICOS CORPORATION,

Defendant-Appellee.

Robert S. Brennan, Miles & Stockbridge P.C., of Baltimore, Maryland, argued for plaintiff-appellant. With him on the brief were Donald E. English, Jr.; Kurt C. Rommel and James T. Carmichael, of McLean, Virginia. Of counsel were Leona Marx and David Williams, II, Vanderbilt University, of Nashville, Tennessee.

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Appealed from: United States District Court for the District of Delaware

Judge Sue L. Robinson

United States Court of Appeals for the Federal Circuit

2009-1258

VANDERBILT UNIVERSITY,

Plaintiff-Appellant,

v.

ICOS CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware
in case no. 05-CV-506, Judge Sue L. Robinson.

DECIDED: April 7, 2010

Before MICHEL, Chief Judge, CLEVENGER and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge CLEVENGER. Opinion concurring in part and dissenting in part filed by Circuit Judge DYK.

CLEVENGER, Circuit Judge.

This is an appeal from the United States District Court for the District of Delaware in a patent action that Vanderbilt University ("Vanderbilt") brought against ICOS Corporation ("ICOS") on July 20, 2005. Vanderbilt filed suit under 35 U.S.C. § 256 alleging that Vanderbilt scientists Jackie D. Corbin ("Dr. Corbin"), Sharron H. Francis ("Dr. Francis"), and Sekhar R. Konjeti ("Dr. Konjeti") (collectively the "Vanderbilt Scientists") should be added as joint inventors on U.S. Patent Nos. 5,859,006 ("the '006

patent") and 6,140,329 ("the '329 patent"). The district court rendered its findings of fact and conclusions of law in a January 27, 2009 opinion. Vanderbilt Univ. v. ICOS Corp., 594 F. Supp. 2d 482 (D. Del. 2009). The district court entered final judgment on January 29, 2009, concluding that Vanderbilt failed to prove that the Vanderbilt Scientists are joint inventors of the '006 and '329 patents. Vanderbilt appeals the district court's final judgment. For the reasons stated below, we affirm.

I

This case involves compounds and methods for treating erectile dysfunction, including the compound known as tadalafil, a PDE5 inhibitor and the active ingredient in the drug Cialis®. PDE5 is a phosphodiesterase enzyme found in smooth muscle cells that binds to and hydrolyzes or breaks down cGMP, a cyclic nucleotide found in smooth muscle tissues. In normal function, cGMP binds with and activates a cGMP-dependent protein kinase which results in relaxation and dilation of the smooth muscle cell. PDE5 inhibitors bind to PDE5 and prevent it from binding with and breaking down cGMP.

Drs. Corbin and Francis are employed by Vanderbilt University and were among the first to discover PDE5 in the late 1970s. Since that time, Drs. Corbin and Francis have worked on both the development of cGMP analogs and PDE5 related research.

In December 1988, Dr. Corbin submitted a research proposal to Glaxo Inc. ("Glaxo")[1] requesting it sponsor his research to develop cGMP analogs. The proposal

[1] Glaxo Inc., later renamed Glaxo Wellcome Inc., was a North Carolina corporation that merged with SmithKline Beecham to form Glaxo SmithKline in 2001. Glaxo Group Limited ("Glaxo U.K.") was a U.K.-based subsidiary of Glaxo. At all times relevant to this litigation, Glaxo maintained a research facility in Les Ulis, France ("Glaxo France"). The patents in suit list a Glaxo France scientist as the sole inventor and are assigned to ICOS.

listed new cGMP analogs that Dr. Corbin hoped would activate cGMP-dependent protein kinase.

In June 1989, Glaxo entered into an agreement with Dr. Corbin through Glaxo's "Cardiovascular Discovery Grant" program to underwrite the Vanderbilt Scientists' research of cGMP analogs. Under the agreement, the University retained ownership of intellectual property, but Glaxo was granted a license agreement to any discoveries. During the three years of the program, Drs. Corbin, Francis, and Konjeti submitted numerous presentations and progress reports to Glaxo.

In November 1990, Dr. Corbin sent an abstract to Glaxo U.K. disclosing his discovery that the potency of cGMP analogs is enhanced by adding a phenyl ring at the 8-position. Meanwhile, the Vanderbilt Scientists continued to work on improving potency with new cGMP analogs. In May 1991, however, Glaxo indicated to Dr. Corbin its concern that cGMP analogs do not work well as orally-administered drugs and encouraged the Vanderbilt Scientists to shift their future focus to PDE5 inhibitors.

Outside of the Glaxo program, the Vanderbilt Scientists continued to work on other research interests. In November 1991, the Vanderbilt Scientists applied the results of their cGMP analog research to synthesize a new PDE5 inhibitor. The Vanderbilt Scientists used a 3-isobutyl-1-methylxanthine ("IBMX") compound because it was a cheap and readily available PDE5 inhibitor that is easily substituted at the 8-position. Building upon their earlier research, the Vanderbilt Scientists attached a phenyl ring to the 8-position of the compound and attached an electron-donating hydroxyl group at the 4 position of the phenyl ring. By applying the results of their cGMP research to IBMX, the Vanderbilt Scientists created a PDE5 inhibitor they thought

was 160 times more potent in inhibiting PDE5 than the original IBMX molecule. Dr. Corbin drafted a letter to Vanderbilt's general counsel disclosing possible therapeutic uses for the new IBMX analogs, including the treatment of male impotence.

In December 1991, during discussions regarding a new research agreement, Dr. Corbin mentioned Vanderbilt's work on PDE5 inhibitors to Dr. Barry Ross, a scientist at Glaxo U.K. On January 3, 1992, Dr. Corbin sent a research proposal to Glaxo U.K. detailing the test results of the cGMP analogs developed under the first research agreement. In the proposal, Dr. Corbin also described the Vanderbilt Scientists' IBMX analog that was 160-fold more potent as a PDE5 inhibitor than the original IBMX molecule. Dr. Corbin explained the Vanderbilt Scientists' overall strategy that "the potencies of existing inhibitors . . . could be enhanced by appending groups that would allow the inhibitors to more closely resemble the entire cyclic GMP molecule." Dr. Corbin proposed that Glaxo fund the Vanderbilt Scientists' work on PDE5 inhibitors going forward. Dr. Corbin also noted in the January letter that "the cG kinase has important disease-related functions other than the induction of vascular smooth muscle relaxation." Male impotence was listed as an area of interest, though Glaxo was not researching male impotence at the time.

On February 3, 1992, Drs. Corbin and Francis met with Dr. Ross regarding the January proposal. Later that month, on February 24, Dr. Corbin sent a more detailed research proposal to Dr. Ross which disclosed the exact design of the Vanderbilt IBMX analog. The detailed research proposal also identified a table of IBMX and zaprinast[2]

[2] Zaprinast was the most powerful known PDE5 inhibitor at the time of the research proposal.

analogs that Vanderbilt proposed for further testing. Many of the listed compounds contain what Vanderbilt now refers to as the "Vanderbilt Structural Features" of Vanderbilt's IBMX analog.

On March 11 and 12, 1992, Glaxo France tested 26 compounds for PDE5 inhibition, including a compound it designated GR35273x.

On April 8, 1992, Dr. Ross forwarded copies of Vanderbilt's February 24, 1992 proposal to six Glaxo scientists, including Dr. Richard Labaudiniere, the head of chemistry and leader of the PDE5 project at Glaxo France.

On April 23, 1992, Glaxo France tested 29 compounds for PDE5 inhibition, including a beta-carboline compound designated GR30040x. Vanderbilt claims all of the tested compounds make some use of the Vanderbilt Structural Features with 11 of the 29 compounds containing nearly all of the Vanderbilt Structural Features. Based on the PDE5 inhibition test results, Dr. Labaudiniere identified GR30040x as a lead compound for further research on PDE5 inhibition. Dr. Labaudiniere assigned the further GR30040x research to Dr. Alain Claude-Marie Daugan, the named inventor on the patents at issue, as a separate study. In the course of testing various modifications to the GR30040x compound between June 1992 and January 1994, Dr. Daugan discovered tadalafil, the claimed compound at issue in this case.

II

In 1991, Glaxo assigned to ICOS the rights, title, and interest in the compounds covered by the patents at issue. Vanderbilt brought this suit under 35 U.S.C. § 256 against ICOS to correct inventorship of the '006 and '329 patents. Vanderbilt asserts that the Vanderbilt Scientists should be added as joint inventors. According to

Vanderbilt, the GR30040x compound could not have been identified by Dr. Labaudiniere as the lead compound without his use of the Vanderbilt Structural Features. Nor could tadalafil have been identified by Dr. Daugan without his reliance on Vanderbilt's work. The district court held a bench trial and found in favor of ICOS.

In its analysis, the district court noted that 35 U.S.C. § 116, the applicable section for joint inventorship, sets "no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor." Vanderbilt Univ. v. ICOS Corp., 594 F. Supp. 2d 482, 504 (D. Del. 2009) (quoting Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997)). The district court further noted that "a person is a joint inventor 'only if he contributes to the conception of the claimed invention.'" Id. (quoting Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1458-59 (Fed. Cir. 2004)). After a summary of the law regarding conception of chemical compounds, the district court concluded that "conception of a chemical substance includes knowledge of both the specific chemical structure of the compound and an operative method of making it" and "does not occur unless one has a mental picture of the structure of the chemical." Id. (quoting Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1230 (Fed. Cir. 1994) and Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1206 (Fed. Cir. 1991)). The district court determined that the Vanderbilt Scientists could not be co-inventors because they never "conceived the specific chemical structure of the compound claimed or the compound with all of its components." Id. at 505 (citations omitted).

To guide its analysis, the district court reviewed our decision in American BioScience and concluded the case contained similar facts and thus controlled its

decision. Id. at 504-05. The district court recognized that in American BioScience we declined to add inventors who provided the "starting materials" for a chemical compound. See Bd. Of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. BioScience Inc., 333 F.3d 1330 (Fed. Cir. 2003) ("American BioScience"). The district court found that "[t]he 'Vanderbilt Structural Features' constitute no more than a 'specific portion[] of a claimed compound' in the language of American BioScience." Vanderbilt Univ., 594 F. Supp. 2d at 505.

The district court concluded that "[b]ecause there is no evidence that [the Vanderbilt Scientists] ever conceived the 'specific chemical structure of the compound' claimed, Burroughs Wellcome, 40 F.3d at 1230, or 'the compound with all of its components,' American BioScience, 333 F.3d at 1340, or communicated that compound to Glaxo, plaintiff has failed to demonstrate by clear and convincing evidence, that Corbin, Francis and Konjeti are coinventors of the patents at issue." Id. The district court noted that "even if the court were to find that plaintiff's disclosure of [the Vanderbilt Structural Features] led to the identification of GR30040x and the subsequent discovery of tadalafil, American BioScience precludes the result plaintiff seeks: namely, that the contribution of a molecular scaffold in the context of one molecule . . . renders the disclosing party or parties inventors of a different family of molecules containing the same scaffold." Id. at 506-07.

Even after reaching the conclusion that its decision was bound by American BioScience, the district court provided a detailed analysis of the remaining facts of the case. First, the court noted that "[t]his is not to say that Corbin, Francis, and Konjeti did not make contributions to Daugan's inventive process; only that, under the applicable

law, these contributions fall more into the category of 'prosaic' contributions because they did not conceive the invention as claimed." Id. at 505. After again reviewing the conflicting stories of the parties, the district court alternatively noted that "the court views plaintiff's theory . . . and defendant's story . . . equally plausible with respect to the identification of GR30040x." Id. at 506. Also, in the absence of any evidence of collaboration between the Vanderbilt Scientists and Dr. Daugan, the district court rejected Vanderbilt's claim to have contributed to Dr. Daugan's identification of tadalafil. Id. at 505-06.

III

We begin by reviewing our case law on joint inventorship. The statutory requirements for joint inventorship are found in 35 U.S.C. § 116 which states, in pertinent part:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

35 U.S.C. § 116 (1988).

Section 116 was amended, in relevant part, in 1984 to clarify the law of joint inventorship by codifying the principles set forth in Monsanto Co. v. Kamp, 269 F. Supp. 818 (D.D.C. 1967). See Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co., Inc., 973 F.2d 911, 916 (Fed. Cir. 1992). The court in Monsanto stated:

> A joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts. To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and

> make some contribution to the inventive thought and to the final result. Each needs to perform but a part of the task if an invention emerges from all of the steps taken together. It is not necessary that the entire invention concept should occur to each of the joint inventors, or that the two should physically work on the project together. One may take a step at one time, the other an approach at different times.

Monsanto, 269 F. Supp. at 824.

In Kimberly-Clark, we applied section 116 to a situation where Proctor & Gamble wished to attribute inventor status to one of its employees who did not collaborate with the named inventor. 973 F.2d at 912-13. While both employees worked on the same subject matter, the court noted that the named inventor "worked alone and was completely unaware of earlier work done by other [] employees." Id. at 913. The court reviewed the amendments and Monsanto and stated that:

> For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestions at a meeting. Here there was nothing of that nature. Individuals cannot be joint inventors if they are completely ignorant of what each other has done until years after their individual efforts. They cannot be totally independent of each other and be joint inventors.

Kimberly-Clark, 973 F.2d at 917.

A primary focus of section 116 has thus always been on collaboration and joint behavior. A person must contribute to the conception of the claimed invention to qualify as a joint inventor. Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004). Yet, each contributor need not have their own contemporaneous picture of the final claimed invention in order to qualify as joint inventors. See Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997) ("One need not alone conceive of the entire invention, for this would obviate the concept of joint invention."). Rather, "the

qualitative contribution of each collaborator is the key – each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." Burroughs Wellcome Co. v. Barr Labs. Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994). The interplay between conception and collaboration requires that each co-inventor engage with the other co-inventors to contribute to a joint conception.

Inventorship is a question of law that we review without deference. Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). We review the underlying findings of fact for clear error. See Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997).

IV

Vanderbilt raises two arguments on appeal. First, Vanderbilt argues that its disclosure of the Vanderbilt Structural Features led to Glaxo France's identification of the GR30040x molecule incorporating the same molecular scaffold. In this regard, the gist of Vanderbilt's case is that Dr. Labaudiniere could only have identified GR30040x by using the Vanderbilt Structural Features. Second, Vanderbilt alleges that the key modification to GR30040x that yielded tadalafil was the addition of an electron-donating substituent on the phenyl ring based upon the work of the Vanderbilt Scientists.

There is no dispute raised between the parties regarding the district court's finding that Dr. Labaudiniere at Glaxo France identified GR30040x as a lead compound for research regarding PDE5 inhibition. Thus, as all relevant contact between the Vanderbilt Scientists and Glaxo occurred at Glaxo U.K., Vanderbilt attempts to piece together sufficient facts to demonstrate that the Vanderbilt Structural Features must have been used by Dr. Labaudiniere to identify GR30040x. As Vanderbilt's argument is

based largely upon criticizing ICOS's evidence regarding how GR30040x was recognized, we first review Glaxo's version of the story.

ICOS contends that Dr. Labaudiniere independently discovered the compounds to be tested for PDE5 inhibition through his knowledge of beta-carbolines and their vasorelaxation effect. This theory can be found in a paper received by the Journal of Medicinal Chemistry on February 5, 2003, entitled "The Discovery of Tadalafil: A Novel and Highly Selective PDE5 Inhibitor." According to Glaxo, Dr. Labaudiniere became aware of the vasorelaxation effect of beta-carbolines from his review of two references: a 1983 article in the European Journal of Pharmacology ("the Koe article") and a May 1992 article in the Journal of Pharmacology and Experimental Therapeutics ("the Elgoyhen article"). Glaxo claims that Dr. Labaudiniere identified two beta-carboline compounds, β-CEE and GR35273x, in March 1992 as potential PDE-5 inhibitors. Dr. Labaudiniere then searched an internal database in April 1992 with the beta-carboline core structure of these two molecules and his search yielded GR30040x. Glaxo's internal "PDE V Inhibitors Project Annual Report for the Year Ending 30/4/93" confirms this story.

Vanderbilt takes issue with Glaxo's story because Glaxo's internal testing records indicate that GR30040x was first tested by Glaxo on April 23, 1992. The Elgoyhen article was not published until May 8, 1992. As the district court found, GR30040x could not have been identified based upon the Elgoyhen reference.

At trial, ICOS backed away from the Elgoyhen story and instead argued that Dr. Labaudiniere took GR35273x from another Glaxo program and tested it on March 11 and 12, 1992 for PDE5 inhibition. According to ICOS, Dr. Labaudiniere

undertook substructure searches using the tetrahydro beta-carboline scaffold of GR35273x, based upon the "impressive" PDE5 inhibition results and his knowledge from the Koe article, and identified GR30040x, among other compounds. ICOS points to the large number of tetrahydro beta-carbolines tested between March and July 1992 to support its theory.

ICOS also points to Glaxo documents to corroborate various details of its story. For example, the minutes of a Glaxo Cardiovascular Research Management Committee meeting in April 1992 describe GR35273x as a compound used in a different study. In the June 1992 minutes, the same committee noted that GR35273x displayed a high PDE5 inhibition activity and noted that Glaxo was starting a program testing GR35273x analogs. At the same meeting, GR30040x was identified as a new PDE5 inhibitor.

ICOS also points to testimony of Dr. Labaudiniere and Dr. Daugan to corroborate its theory on the identification of GR30040x. Dr. Labaudiniere testified that he did not have any knowledge about the Vanderbilt Scientists' research until June 1993, he did not consider IBMX as a starting point for his work on PDE5 inhibitors, and he was not aware of anyone at Glaxo France using data relating to IBMX analogs or trying to develop PDE5 inhibitors that would resemble cGMP. Dr. Daugan confirmed his recollection matches that of Dr. Labaudiniere. In sum, ICOS argues that Vanderbilt's case fails for lack of evidence of any joint collaboration on the invention since neither of the Glaxo France scientists had any knowledge of the work of the Vanderbilt Scientists when they did their work relating to the discovery of tadalafil.

Vanderbilt argues a different view of the same facts. First, Vanderbilt points out that GR30040x is never identified in any Glaxo documents as a GR35273x analog.

Vanderbilt also argues that a GR35273x substructure search would not yield GR30040x because no documents demonstrate that Glaxo identified the beta-carboline structure in GR35273x as significant until October 1992. Finally, Vanderbilt argues that Glaxo lacks credibility as it had previously claimed GR30040x was identified from a β-CEE search until that was proven false. In sum, Vanderbilt attacks Glaxo's story based upon missing documentary evidence.

Vanderbilt instead proposes that Dr. Labaudiniere reviewed the February 1992 research proposal and conducted a substructure search based upon the Vanderbilt IBMX analog. Vanderbilt points out that in April, just weeks after receiving the February proposal, Glaxo France tested 29 compounds for PDE5 inhibition. Vanderbilt points out a number of structural similarities between the tested compounds and its February research proposal.

Vanderbilt's second argument is that after the GR30040x project was assigned to Dr. Daugan, he added to tadalafil an additional element of the Vanderbilt Structural Features by replacing the pyridine ring in GR30040x with a combination of a phenyl ring and an electron-donating methoxy substituent. Vanderbilt argues that this modification directly uses the results of the Vanderbilt Scientists' research. ICOS responds that the modifications were all part of a standard trial and error procedure that would be tried with any molecules of interest.

The only evidence of record regarding Glaxo's modifications to GR30040x is the testimony of Dr. Daugan and Dr. Labaudieniere. Dr. Daugan testified that "[t]he first thing [he] did in this series was explore the replacement of the pyridinyl[] moiety with other heterocyclic or aromatic moieties." Dr. Labaudiniere testified that there are a

standard group of substitutions or additions that would be tried with any molecules of interest. Dr. Labaudiniere characterizes the modifications leading to tadalafil as "obvious" and conducted in a "trial-and-error" fashion. There is no testimony or documentary evidence demonstrating a link between the Vanderbilt Scientists and Dr. Daugan prior to the identification of tadalafil. Indeed, Vanderbilt admitted in the district court that it had no direct evidence to support its view of the facts; instead Vanderbilt argued that it "need not prove specifically how that occurred, but simply how it logically could have occurred."

V

Vanderbilt's challenge to the stated inventorship of the '006 and '329 patents turns on competing claims to inventorship of GR30040x and to tadalafil. As explained above, Vanderbilt admits that no direct evidence supports its claims to joint inventorship. Nonetheless, Vanderbilt argues that Dr. Labaudiniere could not have identified GR30040x as a lead compound independently; nor could Dr. Daugan have identified tadalafil on his own. ICOS counters Vanderbilt's arguments with direct evidence supporting Dr. Labaudiniere's claim to sole identification of GR30040x and with similar direct evidence pointing to Dr. Daugan's independent discovery of tadalafil.

To succeed on its claim to joint inventorship, Vanderbilt must prevail by clear and convincing evidence. Our precedent has long required proof of misjoinder or nonjoinder of co-inventors by clear and convincing evidence.[3] See Eli Lilly & Co. v. Aradigm

[3] Vanderbilt recognizes that the clear and convincing evidence test for correction of inventorship is settled law which binds the court. It suggests that the law should be changed to a lower standard of proof, namely preponderance of the evidence, and that under the lower test it should prevail in this case. We express no view on whether Vanderbilt would prevail under a preponderance of the evidence test.

Corp.,376 F.3d 1352, 1364 (Fed. Cir. 2004); Ethicon v. U.S. Surgical Corp., 135 F.3d 1456, 1460-61 (Fed. Cir. 1998); Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997). The district court correctly concluded that Vanderbilt failed to meet its burden.

We find no clear error in the district court's factual findings underpinning its determination regarding Glaxo's identification of GR30040x. The district court noted that "there is a close proximity in time of the relevant events which renders plausible plaintiff's theory that Glaxo did take note of [the Vanderbilt IBMX compound] and incorporated the 'Vanderbilt Structural Features' into the beta-carboline research it was conducting." Vanderbilt Univ. v. ICOS Corp., 594 F. Supp. 2d 482, 506 (D. Del. 2009). However, after a thorough review of all of the evidence, the district court concluded "the court views plaintiff's theory (which is devoid of evidence regarding the alleged substructure searches based on [the Vanderbilt IBMX compound]) and defendant's story (which is devoid of the aforementioned foundation) equally plausible with respect to the identification of GR30040x." Id. We agree that Vanderbilt fails to present clear and convincing evidence to support its argument that the work of the Vanderbilt Scientists was appropriated by Dr. Labaudiniere for his substructure search.

As for Vanderbilt's argument that Dr. Daugan made use of the Vanderbilt Scientists' research for the modifications to GR30040x, the district court noted that "plaintiff admitted that Corbin, Francis and Konjeti never had any direct communication with Daugan regarding this subject matter." Id. at 505 n.50. The district court also

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Vanderbilt is of course free to seek en banc reconsideration of our settled law on this issue.

noted "a lack of evidence" supporting Vanderbilt's request for an inference that Dr. Labaudiniere communicated the Vanderbilt Structural Features to Dr. Daugan. Id. There is nothing in the record to suggest that these factual findings are erroneous. Thus, Vanderbilt also fails to present clear and convincing evidence to support its argument that the modifications to GR30040x by Dr. Daugan made use of the Vanderbilt Scientists' research.

VI

Vanderbilt makes much of what it perceives to be an error of law committed by the district court. We agree that the district court opinion contains some erroneous statements regarding the law of joint inventorship and a misunderstanding of the relevance of American BioScience to the facts of this case. These errors, however, do not affect the outcome of this appeal and are therefore harmless in context. When tested by the correct law, the facts of the case still require affirmance.

The district court understood our decision in American BioScience to require that each co-inventor have an independent conception of the final compound for a chemical invention. The district court ruled that because the Vanderbilt Structural Features constitute no more than a portion of a claimed compound, the Vanderbilt Scientists cannot, as a matter of law, be joint inventors. Vanderbilt Univ., 594 F. Supp. 2d at 505. The district court hinged this portion of its opinion on the following language from American Bioscience:

> Having in mind specific portions of a claimed compound is not the same as conceiving the compound with all of its components. One must have a conception of the specific compounds being claimed, with all of their component substituents . . . .

333 F.3d at 1340. Yet, when this language from American BioScience is reviewed in context, the district court's error is clear.

The portion of the opinion quoted by the district court phrased the question under review as "whether the district court erred in determining that the FSU scientists were true inventors of the claimed compounds." Id. (emphasis added). In American BioScience the court was faced with choosing between two competing groups of inventors.

Prior to the invention of the compounds at issue in American BioScience, Dr. Tao, a scientist at Florida State University ("FSU"), left FSU to join a group of scientists at American BioScience that were working on similar subject matter. Id. at 1333-35. Shortly after Dr. Tao joined American BioScience, the company filed a patent application that led to the patent in suit, which claimed three taxol analog compounds. The patent named Dr. Tao and three American BioScience scientists as joint inventors. In the district court, FSU claimed that the patent named the wrong inventors. FSU asserted that three of its scientists, along with Dr. Tao, were the correct team of joint inventors. The district court reviewed the evidence on behalf of both competing teams of joint inventors, and concluded that the FSU team was the true group of joint inventors. Accordingly, the district court ordered that the three American BioScience scientists be removed from the patent and the patent be corrected to add the three FSU scientists as inventors. Bd. of Educ. v. Am. BioScience, Inc., No. 4:99cv131/RV, 2001 WL 34104924, at *11 (N.D. Fla. 2001).

American BioScience appealed to this court, arguing clear error in the fact findings made by the district court to support its correction of inventorship. Because the

record provided no evidence of conception by any of the FSU scientists, acting individually or together, this court found clear error in awarding inventorship to the FSU joint inventor team. Properly understood, American BioScience correctly states the law governing joint inventorship. Absent conception within an inventorship team, there can be no invention.

This court began its inquiry with the statement that "[i]nvention requires conception, and 'conception does not occur unless one has a mental picture of the structure of the chemical . . . or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property.'" American BioScience, 333 F.3d at 1340 (quoting Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991)). This court held that the FSU group could not have been the true inventors unless the group had a complete mental picture of the structure of the chemical compounds at issue, and continued its analysis with the language relied upon by the district court. See id. at 1340 ("One must have a conception of the specific compounds being claimed, with all of their component substituents, and the record does not support a finding that [anyone in the FSU group] conceived the three claimed compounds . . . .").

While it is true that the court used the term "one" in reference to conception, it is apparent from context that the court was referring to "the inventor" or, in the case of joint inventors, "the group of inventors." Thus, in American BioScience, the court found that the FSU inventors were not part of any group or collaboration that together envisioned the final claimed compounds. This is because "[w]hile Holton may have invented many of the compounds synthesized in his laboratory . . . there is nonetheless

no evidence of conception by Holton or anyone else at FSU of analogs having the [required combination of molecules]." Id. at 1341. The court's finding in American BioScience was premised on the fact that the FSU and American BioScience scientists were not working together, but rather competing for the patent rights in the compounds at issue. There was no evidence of conception within the FSU group, and this court found sufficient evidence of conception within the American BioScience group.

Vanderbilt is correct that the district court erred in reading American BioScience to find that each co-inventor must have an independent mental picture of the complete compound claimed. Such an interpretation is clearly wrong under our established precedent. Instead, a group of co-inventors must collaborate and work together to collectively have a definite and permanent idea of the complete invention. Similarly, the district court's statement that "the contribution of a molecular scaffold in the context of one molecule" could never rise to the level of joint inventorship for "a different family of molecules containing the same scaffold" is in error. Vanderbilt Univ., 594 F. Supp. 2d at 506-07. "The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Our case law was not intended to create such a bright line rule as was used by the district court.

As previously stated, the district court, however, did not rest its opinion solely on this interpretation of our case law. The district court correctly noted that conception requires identification of the specific chemical structure of the compound. The parties agree that Dr. Daugan was the first to conceive of tadalafil. After a careful review of the evidence, the district court concluded that the parties' respective stories about whether

the Vanderbilt Scientists contributed to the identification of GR30040x were "equally plausible" and that Vanderbilt failed to produce any evidence of joint invention of tadalafil. For Vanderbilt to succeed in its inventorship claim, it must carry its burden of proof of demonstrating that the Vanderbilt Scientists contributed to the claimed invention with clear and convincing evidence. See Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997). The district court's findings demonstrate that under the correct legal test, Vanderbilt did not carry its burden. Thus, any erroneous interpretations of our case law were harmless error.

COSTS

No costs.

AFFIRMED

United States Court of Appeals for the Federal Circuit

2009-1258

VANDERBILT UNIVERSITY,

Plaintiff-Appellant,

v.

ICOS CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware
in case no. 05-CV-506, Judge Sue L. Robinson.

DYK, Circuit Judge, concurring in part and dissenting in part.

There is no question that the district court applied the wrong standard for joint inventorship. The majority agrees, and I agree. However, I respectfully dissent from the majority's conclusion that the district court's legal error was harmless, because in my view, the findings are either contradictory or infected by the court's legal error. I would vacate the judgment and remand, requiring the district court to make findings of fact in light of the correct law.

I

Vanderbilt University ("Vanderbilt") argues that its scientists—Drs. Jackie D. Corbin, Sharron H. Francis, and Sekhar R. Konjeti ("the Vanderbilt scientists")—should be added as joint inventors to the patents in suit under two theories: (1) Dr. Richard Labaudiniere ("Labaudiniere") at Glaxo, Inc. ("Glaxo") used the Vanderbilt scientists' disclosure of 8-(4-hydroxy phenylthio)-IBMX to identify the compound GR30040x, which

was in turn used by Dr. Alain Daugan ("Daugan"), the sole inventor listed on the patents in suit, and (2) Daugan used the Vanderbilt scientists' disclosure of 8-(4-hydroxy phenylthio)-IBMX to modify GR30040x and create the patented compounds. ICOS Corporation ("ICOS")[1] responds that the Vanderbilt scientists' disclosure played no role in Glaxo's identification of GR30040x or the patented compounds. I agree with the majority that the district court's findings with respect to the second theory are not clearly erroneous. The court found that Daugan did not himself directly utilize the Vanderbilt scientists' contributions; this finding was supported by Daugan's testimony that he was not aware of the contributions and Labaudiniere's testimony that he did not forward the Vanderbilt scientists' work to Daugan.

However, the findings with respect to the first theory were either tainted by the district court's legal error or are contradictory on their face. The district court found that the Vanderbilt scientists did in fact make contributions to Glaxo's work, a point the majority ignores. After incorrectly explaining that the Vanderbilt scientists could not be joint inventors because there was no evidence that they had ever conceived the complete patented compound, the district court went on to state:

> This is not to say that Corbin, Francis and Konjeti did not make contributions to Daugan's inventive process; only that, under the applicable law, these contributions fall more into the category of "prosaic" contributions because they did not conceive the invention as claimed.

Vanderbilt Univ. v. ICOS Corp., 594 F. Supp. 2d 482, 505 (D. Del. 2009) (quoting Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358–59 (Fed. Cir. 2004)) (emphases added). The district court also found that ICOS's position that Glaxo made no use of

[1] In 1991, Glaxo and ICOS entered into a collaboration agreement wherein all rights, title, and interest in the compounds ultimately covered by the patents in suit were assigned to ICOS.

the Vanderbilt scientists' disclosures was "untenable." Id. at 505–06. It further stated that ICOS "loses credibility in the court's view for failing to acknowledge that Glaxo made any use of plaintiff's disclosure." Id. at 506. The court even cited a number of factors supporting its finding that Glaxo relied on the Vanderbilt scientists' work in Glaxo's research: the disclosed potency of 8-(4-hydroxy phenylthio)-IBMX, the common structure of the compounds, and the short time between the Vanderbilt disclosure and Glaxo's identification of GR30040x. Id. at 505–06.

At the same time, the district court found that ICOS's theory as to how Labaudiniere identified GR30040x was unsupported. Prior to trial, ICOS asserted that Labaudiniere identified GR30040x by following up on research reported in two journal articles. Id. at 496. But after it was shown that one of those articles was not published until after GR30040x had been tested, ICOS offered a different story at trial. ICOS claimed that Labaudiniere arrived at GR30040x by performing substructure searches based on the tetrahydro beta-carboline fragment of GR35273, a compound discovered in a separate Glaxo program. See id. at 497–98. However, the district court noted that "nowhere in its papers did [ICOS] articulate why Labaudiniere selected tetrahydro beta-carbolines (more specifically, the tetrahydro beta-carboline fragment of GR35273) for his substructure searches." Id. at 506.

Thus the district court found that the Vanderbilt scientists did make a contribution to the identification of GR30040x. The district court then went on to find that "[Vanderbilt]'s theory (which is devoid of evidence regarding the alleged substructure searches based on 8-(4-OH-PT)-IMBX [sic]) and [ICOS]'s story (which is devoid of the aforementioned foundation) [are] equally plausible with respect to the identification of

GR30040x." Id. at 506 (emphasis added). As a footnote to this finding, the district court added: "Notably, even if GR30040x were the invention, the balance would not so tip in favor of plaintiff such as to constitute clear and convincing evidence." Id. at 506 n.53.

II

There are two possible ways to interpret the district court's findings, either of which requires a remand. The first is that the district court's findings are directly contradictory. The court could not have properly found that the Vanderbilt scientists made a contribution to the identification of GR30040x if it were "equally plausible" that they did not make a contribution. In this situation, we must send the case back to the district court so that it can reconsider its findings. Both this circuit and other circuits have uniformly found that judgments based on contradictory findings cannot stand. See, e.g., Essex Electro Eng'rs, Inc. v. Danzig, 224 F.3d 1283, 1295 (Fed. Cir. 2000); Mattson v. Dep't of Treasury, 86 F.3d 211, 215 (Fed. Cir. 1996); Lyles v. United States, 759 F.2d 941, 944 (D.C. Cir. 1985); Grano v. Dep't of Dev. of City of Columbus, 637 F.2d 1073, 1081–82 (6th Cir. 1980); Legate v. Maloney, 334 F.2d 704, 708 (1st Cir. 1964).

The alternative is that the district court found that Vanderbilt did not establish by clear and convincing evidence that the Vanderbilt scientists' contributions were sufficient to make them joint inventors. The problem with this interpretation of the finding is that it is obviously tainted by the district court's view that in order to be joint inventors, the Vanderbilt scientists must have "conceived the 'specific chemical structure of the compound' claimed or 'the compound with all of its components,' or communicated that compound to Glaxo." Vanderbilt, 594 F. Supp. 2d at 505 (citations

omitted). In particular, the district court misinterpreted our decision in American Bioscience when it stated that the Vanderbilt scientists could not be joint inventors "even if the court were to find that [their] disclosure of 8-(4-OH-PT)-IMBX [sic] led to the identification of GR30040x and the subsequent discovery of [the patented compounds]" because "the contribution of a molecular scaffold in the context of one molecule . . . [could not] render[] the disclosing party or parties [joint] inventors of a different family of molecules containing the same scaffold." Id. at 506–07; see Bd. of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. BioScience, Inc., 333 F.3d 1330 (Fed. Cir. 2003). The majority correctly rejected this legal error. See Majority Op. at 19.

An alleged joint inventor does not have to conceive of the entire claimed invention, as the district court mistakenly required. He merely must contribute to the conception of the claimed invention. Eli Lilly, 376 F.3d at 1359. There is "no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). The law does not require that the joint inventors physically work together or at the same time, or each make the same level of contribution. 35 U.S.C. § 116; see also Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917 (Fed. Cir. 1992) (providing "one inventor seeing a relevant report and building upon it" as an example of joint inventive effort). A joint inventor need only "make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." Fina Oil, 123 F.3d at 1473. While the district court found that the Vanderbilt scientists made some contribution, it has not told us exactly what that contribution was or why that contribution

was not enough to make the Vanderbilt scientists joint inventors under the correct standard. If the Vanderbilt scientists made contributions, as the district court found, the fact that those contributions may not have been "appropriated by Dr. Labaudiniere for his substructure search," Majority Op. at 15, does not foreclose the possibility that the Vanderbilt scientists' contribution was sufficient to make them joint inventors.

Because the district court's findings were either contradictory or tainted by legal error, I think we must vacate the judgment of the district court and remand in order that the court may make factual findings under the proper law. I dissent from the majority's decision to affirm what I view as an untenable district court decision.