IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Senior District Judge Richard P. Matsch

Civil Action No. 08-cv-00332-RPM

REINER RIEZLER and
SEVERI MED GmBH,

Plaintiffs,

v.

ROBERT H. ALLEN,
SALLY P. STABLER,
ROBERT H. ALLEN, AS TRUSTEE OF THE ROBERT H. ALLEN REVOCABLE TRUST, and
METABOLITE LABORATORIES, INC.,

Defendants.

FINDINGS AND CONCLUSIONS ON SCOPE OF EMPLOYMENT

U.S. Patent No. 5,563,126 (the '126 Patent) is entitled "Method for Treatment and Prevention of Deficiencies of Vitamins B_{12}, Folic Acid and B_6." The application for the '126 Patent was filed on December 29, 1992, by Robert H. Allen, assigned to Metabolite Laboratories, Inc. ("Metabolite"), a Colorado corporation, on March 11, 1993, and issued on October 8, 1996, showing Dr. Robert H. Allen and Dr. Sally P. Stabler as the named inventors and Metabolite as assignee. (Ex. B-2.)

In this civil action, Dr. Reiner Riezler, a physician, contends that the invention described in claim 1 of the Patent is based on a concept he developed while working at Ortho Pharma Science GmbH ("OPS"), a German clinical research corporation, on a project to demonstrate the

therapeutic effect of a multivitamin product as required by German law. He asserts that he and the plaintiff Severi Med GmBH, are successors to OPS. OPS conducted two studies in Europe, focusing on three ingredients, vitamin B_{12}, vitamin B_6 and folate (or folic acid) because Dr. Reizler thought them to be the most effective in lowering serum metabolite levels with persons with high levels creating health risks. An epidemiologic study was designed to identify persons with elevated metabolite levels. An intervention study was done to demonstrate that treatment with this combination would result in lower levels, thereby effectively treating a vitamin deficiency. He and a colleague at OPS recruited a network of physicians in Europe to obtain serum samples from patients for laboratory tests.

OPS entered into a written contract in August 1991, titled Consultancy Agreement with the defendant, Dr. Robert H. Allen, as an advisory expert to assist with the epidemiologic study at an hourly rate of $100 plus expenses with a confidentiality clause and recognition that all data was to be treated as the property of OPS. (Pls.' Ex. 3.)

At the same time, Dr. Allen and Metabolite protected Metabolite's proprietary information and technical data from disclosure by OPS in a confidentiality Agreement. (Pls.' Ex. 4.)

Dr. Allen was and is an employee of the University of Colorado ("University"), serving as a Professor of Medicine and Director of the Hematology Division of the University of Colorado Health Sciences Center. His responsibilities include teaching, research, clinical work, and administrative duties. Dr. Allen's research activities have focused on vitamin B and folate deficiencies.

Metabolite is a Subchapter S corporation, incorporated by Dr. Allen, as sole owner, in 1988 to commercialize U.S. Patent No. 4,940,658, issued July 10, 1990, entitled "assay for sulfhydryl amino acids and methods for detecting and distinguishing cobalamin and folic acid deficiency" ("the '658 Patent" or "the assay patent"). Dr. Allen and Dr. Stabler are two of the three named inventors of that invention, known as the Allen B-12 Test. Commercialization of the technology of the'658 Patent was the reason Metabolite was formed.

Metabolite performs clinical assays using University facilities under the terms of three written contracts. One agreement, dated July 11, 1988, is the "Physician Service Agreement, signed by Metabolite, Dr. Allen, and representatives of the University Health Sciences Center, the School of Medicine, and University Physicians, Inc. (Defs.' Ex. A-10.) Dr. Allen agreed to "provide technical expertise, direction, consultation and management services necessary for processing any and all Allen B-12 Tests or tests developed in the future submitted to [Metabolite] by [the licensee of the Allen B-12 Test] or any other laboratory for the period of July 11, 1988 to July 10, 1989." (*Id.* at CU CORA 00030308.) Metabolite agreed to "provide personnel, supplies, facilities and equipment" necessary for processing those tests. Metabolite also agreed to pay the University "the amount of $1.50 per test performed under Dr. Allen's direction." The Physician Service Agreement provided that physicians performing services defined in the agreement would be covered by the University's malpractice insurance. The Physician Service Agreement was for a one-year term, but the parties to that agreement have abided by its terms without signing another written agreement.

An Agreement for Support Services, dated July 11, 1988, permits Metabolite to use University personnel and supplies for the processing of Allen B-12 tests and other tests upon payment of per-test fees to the University for overhead. (Defs.' Ex. A-8.)

A License Agreement, also dated July 11, 1988, between Metabolite and University Research Corporation ("URC") granted Metabolite a revocable license for the use of space, facilities and equipment at the University's Health Sciences Center. (Defs.' Ex. A-9.) As consideration for that license, Metabolite agreed to pay University Research Corporation ("URC") 15.3846% of Metabolite's net income. The license agreement between URC and Metabolite was for a one-year term, but the parties to that agreement have abided by its terms without signing another written agreement.

These arrangements are permitted in the University's Patent Policy described in Exhibit A-1, a brochure produced by the University of Colorado Foundation ("Foundation") entitled "Patent Administration and Technology Transfer at The University of Colorado." University employees are required to comply with the Patent Policy as a condition of their employment. The University Patent Policy includes the option to proceed with in-house patenting directly by the Foundation, paying all the costs and obtaining title to the patent.

The Foundation is a private, non-profit, tax exempt organization which raises funds for the University. It is a separate and distinct from the University with greater flexibility to commercially exploit faculty inventions free from state constitutional and statutory restrictions on the University. A Servicing Agreement dated July 31, 1985, between the University and the Foundation, provides that the Foundation is the assignee of all right, title and interest of the

University in rights to inventions, discoveries and other intellectual property in which the University has an interest.

The Foundation formed URC as a non-profit subsidiary to develop and market faculty-generated research inventions. It hired Colorado Venture Management ("CVM"), a for profit corporation to provide advice to start up companies under the entrepreneurial new venture ("ENV") program designed to foster formation of start-up companies with the potential to commercialize faculty inventions. Metabolite is an example. Kyle Lefkoff, an employee of CVM, described URC by analogy to a venture capital fund. URC participates in the venture by obtaining an interest in equity, a share of profits or a royalty on sales. Although the written license provides for payment to URC of 15.3846% of Metabolite's net income, the Foundation receives those payments.

The Medivitan epidemiologic study began in September 1991. The first phase of the Medivitan studies (the epidemiologic study) began in September 1991 and was mostly completed by December 1991. Dr. Allen assisted OPS with that work by testing serum samples for the presence of elevated metabolite levels. That work was conducted through Metabolite, using University facilities and personnel. Metabolite paid fees to the University on a per-test basis for Metabolite's use of those facilities and personnel.

Metabolite billed OPS for the tests.

In December 1991, Dr. Allen traveled to Germany to discuss the OPS research plan. (Tr. 299:24 - 301:8; Pls' Ex. 208.). In January 1992, OPS sent the protocol for the intervention study to Dr. Allen. (Tr. 301:9-24; Pls.' Ex. 200.)

On February 20, 1992, Dr. Allen sent a confidential letter to Dr. Leon Ellenbogen, the Chief of Nutritional Science for Lederle Consumer Health Products, a division of American Cyanamid Company. (Defs.' Ex. A-14 at MB011542.) Dr. Allen's letter to Dr. Ellenbogen ("the Lederle Letter") described Dr. Allen's idea for a new oral multivitamin preparation for the treatment of patients with deficiencies of vitamin B_{12}, folic acid, and pyridoxine (B_6). In March 1992, Dr. Allen provided Lederle with data from three studies that Dr. Allen believed provided support for his idea. (Defs.' Ex. A-14 at MB011561.) Those studies were the Elderly Outpatient, Nursing Home, and Framingham studies, which Dr. Allen had conducted with Dr. Stabler. Dr. Allen's communications with Lederle did not include any OPS data.

On July 13, 1992, Dr. Allen, Lefkoff, and Dr. Mercure met and discussed a strategy for a license opportunity with Lederle for Dr. Allen's proposed new oral vitamin product. A memorandum prepared by Lefkoff, dated July 15, 1992, summarizes the discussion and conclusions reached at the meeting. (Defs.' Ex A-16, copy attached.)

Dr. Mercure testified that he believed that allowing Metabolite to prosecute the patent was in the University's best interests. He understood that the University would benefit financially if Metabolite licensed the invention because the University had an interest in Metabolite's profits. (Tr. 79:9-17; 81:15-22.) This is factually incorrect. The interest was that of the Foundation, a non-profit entity separate from the University. The defendants attempt to blur that distinction to attempt to use the statutory immunity given to state entities. The Foundation is not a governmental agency. Dr. Mercure said that in-house patenting by the Foundation was not a viable option because that would have required the Foundation to spend money it did not have.

He joined in the expectation that Metabolite could negotiate a better royalty rate than the University could. (Tr. 80:7: 81:4-14.)

Mr. Lefkoff testified that the reason for having Metabolite commercialize the discovery was that Dr. Allen, URC and the University "thought we'd make more money that way." (Tr. 139:6-8.) Mr. Lefkoff described Metabolite as "an existing successful and profitable company devoted toward research and development of its products in this area." He said that the Foundation's patent program was "very limited in their resources." (Tr. 139:114-21.) Mr. Lefkoff said that Metabolite was in a better position to prosecute and defend the patent because Metabolite "had the resources, the expertise, and the cash flow to do so." (Tr. 140:15-24.)

After the meeting, Lefkoff prepared the memo dated July 15, 1992 (Defs.' Ex. A-16) and sent it to Paula Butts, a paralegal at the University's Patent Office.[1] There is no evidence of any response from the University's Patent Office to that memo.

The OPS intervention study was completed in August 1992. The OPS intervention study demonstrated that treatment with the three-vitamin combination resulted in lowering of metabolite levels. OPS shared those results with Dr. Allen.

On December 29, 1992, Dr. Allen filed a patent application for a "Method for Treatment and Prevention of Deficiencies of Vitamins B_{12}, Folic Acid and B_6," naming himself as the inventor. (Def.'s Ex. B-1, Application Number 07/999499, or the "the '499 Application.") The '499 Application included data from four studies – the Elderly Outpatient study, the Nursing

[1]Butts' position at the Foundation is reflected on a letter dated February 27, 1992, to Lefkoff from Butts. (Defs.' Ex. A-14 at MB011558.)

Home study, the Framingham study and the Medivitan study. Data from the Medivitan studies were used to show that treatment with a combination of vitamin B_{12}, B_6, and folate resulted in lower metabolite levels. (Tr. 313-3 – 315:2; Ex. B-1 at MB006139-6141 (Example 2); Ex. B-2 at MB 255 (Example 2).)

On March 11, 1993, Dr. Allen assigned the '499 Application to Metabolite. (Def.'s Ex. B-3.) On March 11, 1993, Dr. Allen – on behalf of Metabolite – signed a declaration claiming small entity status, which was submitted to the PTO for the purpose of determining the applicable filing fees. (Pls.' Ex. 153 at MB006196-97.) The '126 Patent issued to Metabolite on October 8, 1996.[2]

The essence of the plaintiffs' claims in this case is that Dr. Allen and Metabolite used Dr. Riezler's concept and the OPS study data to obtain the '126 Patent without permission and without acknowledging Dr. Riezler as an inventor.

The defendants challenged this court's jurisdiction in a motion pursuant to Fed.R.Civ.P. 12(b)(1), arguing that federal jurisdiction is precluded by the Eleventh Amendment to the United States Constitution and that jurisdiction over the state law claims is barred by the plaintiffs' failure to comply with the notice requirements of the Colorado Governmental Immunity Act ("CGIA"), Colo. Rev. Stat. § 24-10-101 *et seq.*

The defendants' motion was converted to a Rule 56 motion. On July 21, 2009, after the parties had conducted discovery pertaining to the jurisdictional issues, the court heard arguments of counsel and denied the motion. The defendants appealed that order.

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[2]In 1995, Dr. Allen had submitted to the PTO a petition to correct inventorship, adding Dr. Stabler as a named inventor. (Pls.' Ex. 153 at MB 006253- 6258 & MB006268.) Dr. Stabler had assigned any interest in the '499 Application to Metabolite.

In an order dated April 13, 2010, the United States Court of Appeals for the Federal Circuit ruled that summary judgment was appropriate with respect to the Eleventh Amendment claim of immunity, that there is no basis for immunity under the CGIA with respect to acts taken before December 29, 1992, because there are no allegedly wrongful acts taken before that date; and that there is no basis for a claim of immunity on or after March 11, 1993, because any wrongful actions taken after that date were not taken by Dr. Allen and Dr. Stabler within the scope of their employment by the University of Colorado ("University"). The appellate court was unable to conclude from the record whether Dr. Allen and Dr. Stabler were acting within the scope of their University employment between the period of the filing of the first patent application on December 29, 1992, and the assignment of rights to Metabolite on March 11, 1993, and whether Dr. Stabler is alleged to have committed any wrongful acts during that period. The appellate court remanded the record to this court for determination of those issues. The appellate court retains jurisdiction during the pendency of the limited remand.

The plaintiffs do not contend that Dr. Stabler committed any wrongful acts between December 29, 1992 and March 11, 1993. (Tr. at 14:25 – 15:10.) The question presented to this court by the limited remand from the Federal Circuit Court of Appeals is whether Dr. Allen's filing of the patent application and its prosecution up to the date of the assignment to Metabolite was within the scope of his employment by the University and thereby within the statutory immunity for tort liability under the CGIA.

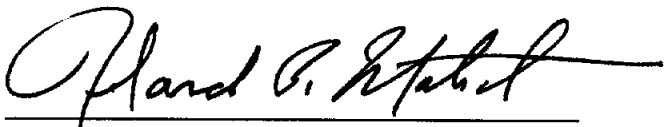
It was not. All of the steps taken to obtain the patent were done by Dr. Allen for himself and Metabolite. The prosecution was by a private law firm and all costs and expenses were paid by Metabolite. All of the decisions made and positions taken were by Dr. Allen for Metabolite,

consistent with the July memo. He did so as a free agent without any direction or control from anyone else at the University. As observed above, the only interest of the University was the expectation of future benefits from the Foundation's share of Metabolite's profits from commercialization of it.

Based on the foregoing, the court finds and concludes that the alleged wrongful conduct of Dr. Allen during the period from December 29, 1992 through March 11, 1993, was not undertaken within the scope of his University employment.

Dated: September 16, 2010

BY THE COURT:



Richard P. Matsch, Senior District Judge