GREENBERG vs. MIAMI CHILDREN'S HOSPITAL RESEARCH INSTITUTE, INC.,

***264 F. Supp. 2d 1064 (S.D. Fla.* 2003)**

MORENO, Judge

This case presents an unfortunate legal dilemma set against the backdrop of a historic breakthrough in the treatment of a previously intractable genetic disorder. Both parties in this case were jointly engaged in a noble and dogged pursuit to detect and find a cure for a fatal genetic disorder called Canavan disease, a rare genetic disease that occurs most frequently in Ashkenazi Jewish families.

Plaintiffs, a group of individuals and non-profit institutions, are attempting to assert legal rights against Defendant researcher and his research institution's commercialization of the fruits of their Canavan disease research. Before the Court is Defendants' Motions to Dismiss . . . for failure to state a claim upon which relief may be granted. Because the Court finds that Plaintiffs have failed to allege sufficient facts as to all their claims except unjust enrichment, the motions are GRANTED in part.

I. BACKGROUND

. . . . The individual plaintiffs . . . are parents of children who were afflicted with Canavan disease. The other Plaintiffs are non-profit organizations that provided funding and information to Defendants to research and discover the Canavan disease gene. Defendants are the physician-researcher, Dr. Reuben Matalon ("Matalon"), Variety Children's Hospital d/b/a Miami Children's Hospital ("MCH"), and the hospital's research affiliate, Miami Children's Hospital Research Institute ("MCHRI").

The Complaint alleges a tale of a successful research collaboration gone sour. In 1987, Canavan disease still remained a mystery - there was no way to identify who was a carrier of the disease, nor was there a way to identify a fetus with Canavan disease. Plaintiff Greenberg approached Dr. Matalon, a research physician who was then affiliated with the University of Illinois at Chicago for assistance. Greenberg requested Matalon's involvement in discovering the genes that were ostensibly responsible for this fatal disease, so that tests could be administered to determine carriers and allow for prenatal testing for the disease.

At the outset of the collaboration, Greenberg and the Chicago Chapter of the National Tay-Sachs and Allied Disease Association, Inc. ("NTSAD") located other Canavan families and convinced them to provide tissue (such as blood, urine, and autopsy samples), financial support, and aid in identifying the location of Canavan families internationally. The other individual Plaintiffs began supplying Matalon with the same types of information and samples beginning in the late 1980s. Greenberg and NTSAD also created a confidenti al database and compilation - the Canavan registry - with epidemiological, medical and other information about the families.

Defendant Matalon became associated in 1990 with Defendants Miami Children's Hospital Research Institute, Inc. and Variety Children's Hospital d/b/a Miami Children's Hospital.

Defendant Matalon continued his relationship with the Plaintiffs after his move, accepting more tissue and blood samples as well as financial support.

The individual Plaintiffs allege that they provided Matalon with these samples and confidential information "with the understanding and expectations that such samples and information would be used for the specific purpose of researching Canavan disease and identifying mutations in the Canavan disease which could lead to carrier detection within their families and benefit the population at large." Plaintiffs further allege that it was their "understanding that any carrier and prenatal testing developed in connection with the research for which they were providing essential support would be provided on an affordable and accessible basis, and that Matalon's research would remain in the public domain to promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure for Canavan disease." This understanding stemmed from their "experience in community testing for Tay-Sachs disease, another deadly genetic disease that occurs most frequently in families of Ashkenazi Jewish descent."

There was a breakthrough in the research in 1993. Using Plaintiffs' blood and tissue samples, familial pedigree information, contacts, and financial support, Matalon and his research team successfully isolated the gene responsible for Canavan disease. After this key advancement, Plaintiffs allege that they continued to provide Matalon with more tissue and blood in order to learn more about the disease and its precursor gene.

In September 1994, unbeknownst to Plaintiffs, a patent application was submitted for the genetic sequence that Defendants had identified. This application was granted in October 1997, and Dr. Matalon was listed as an inventor on the gene patent and related applications for the Canavan disease, Patent No. 5,679,635 (the "Patent"). Through patenting, Defendants acquired the ability to restrict any activity related to the Canavan disease gene, including without limitation: carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations.

Although the Patent was issued in October 1997, Plaintiffs allege that they did not learn of it until November 1998, when MCH revealed their intention to limit Canavan disease testing through a campaign of restrictive licensing of the Patent. Specifically, on November 12, 1998, Plaintiffs allege that Defendants MCH and MCHRI began to "threaten" the centers that offered Canavan testing with possible enforcement actions regarding the recently-issued patent. Defendant MCH also began restricting public accessibility through negotiating exclusive licensing agreements and charging royalty fees.

Plaintiffs allege that at no time were they informed that Defendants intended to seek a patent on the research. Nor were they told of Defendants' intentions to commercialize the fruits of the research and to restrict access to Canavan disease testing.

. . . . Plaintiffs generally seek a permanent injunction restraining Defendants from enforcing their patent rights, damages in the form of all royalties Defendants have received on the Patent as well as all financial contributions Plaintiffs made to benefit Defendants' research. Plaintiffs allege that Defendants have earned significant royalties from Canavan disease testing in excess of $75,000 through enforcement of their gene patent, and that Dr. Matalon has personally profited by receiving a recent substantial federal grant to undertake further research on the gene patent.

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III. ANALYSIS

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A. Lack of Informed Consent

In Count I of the Complaint, the individual Plaintiffs, who served as research subjects, and the corporate plaintiff Dor Yeshorim claim that Defendants owed a duty of informed consent. . . . Defendants breached this duty, Plaintiffs claim, when they did not disclose the intent to patent and enforce for their own economic benefit the Canavan disease gene. . . .

1. Duty to Obtain Informed Consent for Medical Research

[The court rejected a duty for researchers to disclose their economic interests, distinguishing *Moore v. Regents of the University of California* on the ground that the researcher in that case also provided care to Mr. Moore, while the Dr. Matalon did not provide care to any of the plaintiffs.]

B. Breach of Fiduciary Duty

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1. Fiduciary Relationship

Defendants have moved to dismiss this count because Plaintiffs did not plead the elements of a fiduciary relationship. . . . Florida courts have found fiduciary relationships in this context when "confidence is reposed by one party and a trust accepted by the other." This is a two-way relationship, and a fiduciary relationship will only be found when the plaintiff separately alleges that the plaintiff placed trust in the defendant and the defendant accepted that trust. . . .

Defendants assert that the Complaint does not allege any facts that show that the trust was recognized and accepted. . . . Plaintiffs allege, however, that Defendants accepted the trust by undertaking research that they represented as being for the benefit of the Plaintiffs. Compl. P 37 (research purpose defined as "to identify mutations in the Canavan gene which may lead to carrier detection within my family"). . . .

Taking all the facts alleged as true, the Court finds that Plaintiffs have not sufficiently alleged the second element of acceptance of trust by Defendants and therefore have failed to state a claim. There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given. Accordingly, this claim is DISMISSED.

C. Unjust Enrichment

In Count III of the Complaint, Plaintiffs allege that MCH is being unjustly enriched by collecting license fees under the Patent. Under Florida law, the elements of a claim for unjust enrichment are (1) the plaintiff conferred a benefit on the defendant, who had knowledge of the benefit; (2) the defendant voluntarily accepted and retained the benefit; and (3) under the circumstances it would be inequitable for the defendant to retain the benefit without paying for

it. The Court finds that Plaintiffs have sufficiently alleged the elements of a claim for unjust enrichment to survive Defendants' motion to dismiss.

While the parties do not contest that Plaintiffs have conferred a benefit to Defendants, including, among other things, blood and tissue samples and soliciting financial contributions, Defendants contend that Plaintiffs have not suffered any detriment, and note that no Plaintiff has been denied access to Canavan testing. Furthermore, the Plaintiffs received what they sought - the successful isolation of the Canavan gene and the development of a screening test. Plaintiffs argue, however, that when Defendants applied the benefits for unauthorized purposes, they suffered a detriment. Had Plaintiffs known that Defendants intended to commercialize their genetic material through patenting and restrictive licensing, Plaintiffs would not have provided these benefits to Defendants under those terms.

Naturally, Plaintiffs allege that the retention of benefits violates the fundamental principles of justice, equity, and good conscience. While Defendants claim that they have invested significant amounts of time and money in research, with no guarantee of success and are thus entitled to seek reimbursement, the same can be said of Plaintiffs. Moreover, Defendants' attempt to seek refuge in the endorsement of the U.S. Patent system, which gives an inventor rights to prosecute patents and negotiate licenses for their intellectual property fails, as obtaining a patent does not preclude the Defendants from being unjustly enriched. The Complaint has alleged more than just a donor-donee relationship for the purposes of an unjust enrichment claim. Rather, the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene. Therefore, given the facts as alleged, the Court finds that Plaintiffs have sufficiently pled the requisite elements of an unjust enrichment claim and the motion to dismiss for failure to state a claim is DENIED as to this count.

D. Fraudulent Concealment

[The court rejected the fraudulent concealment claim, observing that the plaintiffs did not provide any evidence of fraudulent intent, that the absence of a fiduciary relationship precluded any duty of disclosure to the plaintiffs, that the defendants' patent was a matter of public record and therefore not fraudulently concealed, and that plaintiffs did not suffer any economic inury.]

E. Conversion

The Plaintiffs allege in Count V of their Complaint that they had a property interest in their body tissue and genetic information, and that they owned the Canavan registry in Illinois which contained contact information, pedigree information and family information for Canavan families worldwide. They claim that MCH and Matalon converted the names on the register and the genetic information by utilizing them for the hospitals' "exclusive economic benefit." The Court disagrees and declines to find a property interest for the body tissue and genetic information voluntarily given to Defendants. These were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples, and thus conversion does not lie as a cause of action.

In Florida, the tort of "conversion is an unauthorized act which deprives another of his property permanently or for an indefinite time." Using property given for one purpose for

another purpose constitutes conversion.

First, Plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion. This case is similar to *Moore v. Regents of the University of California*, where the Court declined to extend liability under a theory of conversion to misuse of a person's excised biological materials. The plaintiff in *Moore* alleged that he had retained a property right in excised bodily material used in research, and therefore retained some control over the results of that research. The California Supreme Court, however, disagreed and held that the use of the results of medical research inconsistent with the wishes of the donor was not conversion, because the donor had no property interest at stake after the donation was made. . . .

Second, limits to the property rights that attach to body tissue have been recognized in Florida state courts. For example, *in State v. Powell, 497 So. 2d 1188, 1192 (Fla. 1986),* the Florida Supreme Court refused to recognize a property right in the body of another after death. Similarly, the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party.

. . . . Plaintiffs cite a litany of cases in other jurisdictions that have recognized that body tissue can be property in some circumstances. *See, e.g., Brotherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991)* (aggregate of rights existing in body tissue is similar to property rights); *York v. Jones, 717 F. Supp. 421, 425 (E.D. Va. 1989)* (couple granted property rights in their frozen embryos). These cases, however, do not involve voluntary donations to medical research.

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Finally, although the Complaint sets out that Plaintiff Greenberg owned the Canavan Registry, the facts alleged do not sufficiently allege the elements of a *prima facie* case of conversion, as the Plaintiffs have not alleged how the Defendants' use of the Registry in their research was an expressly unauthorized act. The Complaint only alleges that the Defendants "utilized the information and contacts for their exclusive economic benefit." There is no further allegations of the circumstances or conditions that were attached to the Defendants' use of the Canavan Registry. Nor are there any allegations about any of the Plaintiffs' entitlement to possess the Registry.

The Court finds that Florida . . . law do[es] not provide a remedy for Plaintiffs' donations of body tissue and blood samples under a theory of conversion liability. Indeed, the Complaint does not allege that the Defendants used the genetic material for any purpose but medical research. Plaintiffs claim that the *fruits* of the research, namely the patented material, was commercialized. This is an important distinction and another step in the chain of attenuation that renders conversion liability inapplicable to the facts as alleged. If adopted, the expansive theory championed by Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital. At the core, these were donations to research without any contemporaneous expectations of return. Consequently, the Plaintiffs have failed to state a claim upon which relief may be granted on this issue. Accordingly, this claim is DISMISSED.

F. Misappropriation of Trade Secrets

The Plaintiffs' final claim is that MCH misappropriated a trade secret - the registry of people who had Canavan disease. . . .

The Canavan Registry was not misappropriated by MCH because there is no allegation that MCH knew or should have known that the Canavan Registry was a confidential trade secret guarded by Plaintiffs, and furthermore, that Matalon had acquired through improper means. Plaintiffs' theory that Defendants misappropriated the Registry once Matalon and MCH chose to use the Registry beyond the use for which it was authorized does not pass muster, since there was no explicit authorization that the Registry be used for a certain purpose in the first place. Plaintiffs cannot donate information that they prepared for fighting a disease and then retroactively claim that it was a protected secret.

Accordingly, the Court finds that Plaintiffs have failed to state a claim regarding misappropriation of trade secret as they have not sufficiently alleged the requisite elements to convert the Registry into an actionable trade secret. This claim is therefore DISMISSED. . . .