

Matter of Luft v Clark
2010 NY Slip Op 31488(U)
June 3, 2010
Sup Ct, Suffolk County
Docket Number: 08-19771
Judge: Peter Fox Cohalan
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MEMORANDUM

COPY

SUPREME COURT, SUFFOLK COUNTY

I.A.S. PART 24

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 In the Matter of the Application of :
 :
 BENJAMIN LUFT, M.D., :
 :
 Petitioner, :
 :
 For a Judgment pursuant to Article 78 of the :
 Civil Practice Law and Rules, :
 :
 - against - :
 :
 JOHN B. CLARK, Interim Chancellor, State :
 University of New York, THE BOARD OF :
 TRUSTEES OF THE STATE UNIVERSITY :
 OF NEW YORK, and THE RESEARCH :
 FOUNDATION OF THE STATE UNIVERSITY :
 OF NEW YORK, :
 Respondents.:
 -----X

By: Cohalan, J.S.C.
Dated: June 3, 2010

Index No. 08-19771

Mot. Seq. # 004 - MotD
Mot. Seq. # 005 - MotD
DISPSUBJ

Return Date: 11-25-09 (#004)
Return Date: 12-9-09 (#005)

Adjourned: 11-25-09 (#004)
Adjourned: 12-9-09 (#005)

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Initially this Court grants the alternative relief requested in motion (004) by the respondent Research Foundation of the State University of New York (hereinafter Research Foundation) for permission to file the supplemental affidavit of Heather M. Hage, Esq. and considers the same.

The motion (005) by the respondents John B. Clark, the State University of New York (hereinafter Chancellor), and the Board of Trustees of the State University of New York (hereinafter Board of Trustees), for an order striking the petitioner's reply papers or, in the alternative, for permission to file the affirmation and exhibits in sur-reply to the petitioner's papers is granted to the extent that the moving respondents are permitted to file the affirmation and exhibits in sur-reply.

In this Article 78 proceeding the petitioner seeks a judgment annulling and setting aside the findings and recommendations of the Patents and Inventions Policy Board (hereinafter Patents

Board), and annulling the determination of the Interim Chancellor, who accepted the findings and recommendations of the Patents Board.

This Court finds that the determinations of the respondents were arbitrary and capricious and are unsupported by the evidence in the record and have no rational basis in incorrectly determining the petitioner was not a co-owner of the United States (hereinafter U.S.) Patents Application Serial #10/369,100.

The recommendations of the Ad Hoc Intellectual Property Investigative Committee (hereinafter Ad Hoc Committee) appointed by the Interim Chancellor pursuant to the Patents and Inventions Policy of the State University of New York (hereinafter SUNY) are reinstated and the Chancellor is directed to accept the Ad Hoc Committee determinations, findings and recommendations that the petitioner is a co-owner of the U.S. Patents Application Serial #10/369,100 (hereinafter the 100 application) which is currently limited to 21 patent claims (i.e. originally filed claims 1-19, 46 and 47) and the patents that issue based upon the application; that the petitioner is not required to assign to the Research Foundation his rights in patent claims 1-19 and 46 and 47; and that the remaining claims submitted by the petitioner have been cancelled in response to a Restriction Requirement issued by the U.S. Patents and Trademarks Office and that the petitioner shall assign his rights in patent claims 20-45 and 48-51 that were originally filed in the 100 application, but later cancelled in response to the Restriction Requirement with the understanding by the Ad Hoc Committee that those claims may be re-filed in a divisional patent application, and that the petitioner's interest in such divisional application and corresponding issued patents be assigned to the Research Foundation.

This petition arises from a dispute concerning certain intellectual property and the development of a vaccine pursuant to Lyme disease research and various proteins (OspB, OspC and OspA proteins) conducted by the petitioner and others. At issue is whether the intellectual property belongs to the petitioner, petitioner as co-owner, or to the Research Foundation, whether this intellectual property is a "continuation-in-part" (hereinafter CIP) which was generated as a result of the work in petitioner's private corporation (on his own time and with his own resources) or whether the generation of this particular intellectual property was the result of the use of SUNY's facilities and resources.

The petitioner claims that the Chancellor contravened lawful procedure in an arbitrary and capricious determination and irrational misuse of power by accepting and adopting unfounded and unsound findings and recommendations of an improperly constituted Patents Board which overturned a decision of a properly constituted Ad Hoc Committee appointed by the Interim Chancellor to investigate the petitioner's claim to ownership of this intellectual property. The Ad Hoc Committee, after a hearing and exhaustive review of the materials submitted, determined that the petitioner was the co-owner of certain intellectual property. The petitioner claims that the SUNY respondents thereafter incorrectly determined that the petitioner was not a co-owner of the 100 application in that his research utilized the SUNY facilities, resources, and monies, and that the petitioner had assigned his interest in his future patent rights to the Research Foundation.

The Research Foundation is a private, non-profit educational corporation founded in 1951 for the benefit of SUNY for the purpose of providing services to SUNY consistent with the Research

Foundation's Charter and June 1977 Agreement with SUNY. It is a SUNY division that administers faculty grants and oversees SUNY's intellectual property rights and holds title to all intellectual property solely for the benefit of SUNY. SUNY and its faculty are the beneficiaries of royalties generated from patents held by the Research Foundation. Pursuant to the June 1977 Agreement, SUNY's Patents and Copyright Policy and implementation thereof govern all patents and copyright matters arising from any sponsored programs covered by the June 1977 agreement, and in the event SUNY's Patents and Copyright policy is modified, the Research Foundation shall modify its own patents and copyright policy promptly to conform to the SUNY policy.

In 1996, Brook Biotechnologies, Inc. (hereinafter Brook Bio), a biotechnology company formed by the petitioner, was granted a license by the Research Foundation to commercialize certain intellectual property. The petitioner, as professor and chairman of Medicine and Infectious Diseases at SUNY, made an application on or about November 11, 1998 for a grant from the Department of Health and Human Services Public Health Service for vaccine intervention for Lyme borreliosis. The Research Foundation was listed as the applicant organization. On May 19, 1999 the petitioner who, together with co-inventor John J. Dunn (hereinafter Dunn) Senior Microbiologist from Brookhaven National Laboratory (hereinafter BNL), invented certain improvements in Novel Chimeric Proteins Comprising Borrelia Polypeptides and Uses, (described in an application for Letters Patent of the United States, filed April 29, 1994 as application # 08/235.836) assigned to the Research Foundation their entire right, title and interest in and to said application and such Letters Patent as might issue from it.

LETTER OF FEBRUARY 16, 2005

In his letter, dated February 16, 2005, to Lisa A. Alexander, Esq., Associate Counsel of the Office of SUNY's Counsel, the petitioner stated that in November 1993, he and Dunn filed a patent application entitled "Chimeric Proteins Comprising Borrelia Polypeptides; Uses Therefore" (patent #US 6,248,562), which application described the technology involved in the development of a specific combination of unique polypeptides derived from homologous proteins of *Borrelia burgdorferi*, OspA, as well as specific polypeptides derived from multiple proteins from *Borelia burgdorferi*. One such multiprotein polypeptide was comprised of two highly homologous proteins, OspA and OspB, and a third was derived from three outer surface proteins: OspA, OspB and OspC. The patent was ultimately issued in 2001 and licensed to Brook Bio which received no financial support from SUNY, and paid all licensing fees and patent expenses according to a schedule, and expended millions of dollars on this project. Because the Research Foundation had failed to obtain BNL's review and approval of the Brook Bio license agreement as was required by the cross-licensing agreement between Research Foundation and BNL, Brook Bio was forced to renegotiate the licensing agreement in 1997. After licensing this technology, Brook Bio performed additional research and further developed this technology which ultimately led to the first FDA¹ approved recombinant based diagnostic kit which Brook Bio co-developed with an industrial partner, Chembio.

During the course of the work at Brook Bio, new polypeptides were developed that were not described in the initial patent, including the development of OspC chimeric proteins comprised of polypeptides derived from different OspC homologs and polypeptides comprised of two outer

¹ Food and Drug Administration

surface proteins, OspC and OspA. The petitioner stated that, concurrently, at his laboratory at SUNY Stony Brook, he continued to do separate research projects which were funded by NIH²; that he made full disclosure of all his work at SUNY to the Research Foundation; and that he duly assigned the rights of all work done at SUNY to the Research Foundation. Some of this work involved the development of stability mutants to optimize the thermodynamic stability of the chimeric proteins described in the patent, correlating specific genotypes of *Borrelia burgdorferi* to specific pathotypes, as well as dissecting out key immunologic epitopes of OspC.

The petitioner stated that, at the same time, he and Dunn, in their capacity as officers, principals and/or consultants to Brook Bio, advised and planned for the exploitation of the technology detailed in the patent which had been licensed to Brook Bio. Hamilton, Brook, Smith & Reynolds, P.C. (hereinafter Hamilton Brook), patent counsel representing the Research Foundation and the petitioner, advised that a CIP of the patents licensed to Brook Bio was the way in which to prepare a patent application for "Groups of *Borrelia burgdorferi* and *Borrelia afzelli* that Cause Lyme Disease in Humans" which described a specific group of organisms that expressed a specific subset of OspC proteins that was correlated with human disease; described the preparation of chimeric proteins that contained unique polypeptides derived from homologous OspC proteins from different strains, as well as specific polypeptide derived from OspC and OspA. The petitioner further stated that this latter invention was similar to the OspC-OspA-OspB that was described in the original patent application. He stated that the work embodied in the CIP was performed solely at Brook Bio, and not at SUNY, and that his role of providing guidance and supervision in the on-going research was done on his own time, after his work hours at SUNY, and did not require the use of laboratory animals. In 2003, Hamilton Brook prepared a CIP entitled "Recombinant Constructs of *Borrelia burgdorferi*"; listing the petitioner, Dunn, Dr. Raymond Dattwyler (hereinafter Dattwyler) and Dr. Maria Gomez-Solecki (hereinafter Gomez-Solecki) on the patent application.

The petitioner further stated that in 1998, he approached Baxter Laboratory Pharmaceuticals (hereinafter Baxter) with the idea of entering into an agreement between Brook Bio and Baxter for the development of a vaccine for Lyme disease. Baxter signed a letter of intent and they entered into a prolonged period of negotiation which also involved Baxter substantiating findings in the Baxter Laboratory. Early in the summer of 2002, when at the final stages of negotiations to an agreement with Baxter which included access to technology that Baxter had licensed from SUNY, proprietary information and intellectual property developed at Brook Bio included in the OspC patent and the OspC/A patent, Research Foundation notified Brook Bio that it would no longer extend the Baxter license agreement and that it was taking back the license. Less than a month thereafter, Research Foundation signed a deal with Baxter which included terms that the petitioner had negotiated with Baxter, among which was the licensing of technology developed at Brook Bio, including the CIP. Thereafter, Jack Peterson of the Research Foundation demanded that the petitioner assign to it his rights in and for the intellectual property underlying the 2003 CIP patent application referred to above as the agreement between Baxter and the Research Foundation involved granting a license to the CIP technology which the Research Foundation did not have, but which the petitioner did. The petitioner refused to assign the CIP to the Research Foundation, thus giving rise to the instant dispute.

²National Institute of Health

CONTENTIONS

The respondents contend that because the CIP is linked to the parent patents which the petitioner duly assigned to Research Foundation on May 19, 1999, that the work he performed on the CIP derived new information from the use of SUNY facilities and involved animal testing and therefore the respondents are entitled to assignment of the CIP.

The petitioner contends that his work embodied in the 100 application was performed solely at Brook Bio on his own time after his SUNY work hours and not at SUNY and involved the invention of a specific protein not covered under the initial patent application assigned to the Research Foundation on May 19, 1999. The petitioner claims Brook Bio applied for many grants, some of which included plans for animal testing to be done at SUNY. However, the work that resulted in the CIP was funded by monies obtained by Brook Bio and not by SUNY. Animal testing at SUNY was contemplated in Brook Bio's SBIR³ grant application. Initially, these experiments were to be performed by Dr. William Golde (hereinafter Golde) at SUNY, with reimbursement only for the costs of materials and without any request for inventorship, as specified in the 1997 application for the SBIR submitted by Brook Bio. When Golde left SUNY, the petitioner agreed to do it in his own laboratory at Brook Bio. The petitioner contends that his inventive contribution to some of the specific compositions are separate and apart from the animal testing and therefore are not required to be assigned to the respondents and his work relative thereto was conducted at Brook Bio on his own time.

Due to this dispute, and pursuant to the SUNY Patents Policy, §335.28 Patents and Inventions Policy, (b), an Ad Hoc Committee was appointed by the Chancellor to conduct a hearing and make recommendations to the Chancellor concerning its findings.

PATENTS AND INVENTIONS POLICY OF THE STATE UNIVERSITY OF NEW YORK

SUNY's Patents Policy, as approved by the Board of Trustees on September 19, 1979 and amended on November 16, 1988, at §335.28 Patents and Inventions Policy, (b) provided in relevant part that "All inventions made by faculty members, employees, students, and all others utilizing university facilities at any of the State-operated institutions of State University shall belong to State University and should be voluntarily disclosed, or shall be disclosed to State University upon request of the university. The inventor or inventors shall make application for patents thereon as directed by State University and shall assign such applications or any patents resulting therefrom to or as directed by State University. However, non-university organizations and individuals who utilize university research facilities under the trustee's policy on cooperative use of research equipment, or policy and guidelines on use of State University facilities by emerging technology enterprises, will retain ownership of all patentable inventions. Also, an invention made by an individual wholly on such individual's own time, and without the use of such university facilities, shall belong to the individual even though it falls within the field of competence relating to the individual's university position. For purposes of this provision, an individual's "own time" shall mean the time other than that devoted to normal and assigned functions in teaching, university

³Small Business Innovation Research Program (see, Respondents' Exhibit G of the Patents and Inventions Policy Board of the State University of New York) SBIR is a highly competitive program that encourages small business to explore their technological potential and provides the incentive to profit from its commercialization.

service, direction and conduct of research on university premises and utilizing university facilities. The term "university facilities" shall mean any facility available to the inventor as a direct result of the inventor's affiliation with State University, or any facility available under the trustees' policy on cooperative use of research equipment, or policy on use of facilities by emerging technology enterprises, and which would not otherwise be available to a non-State University affiliated individual. Where any question is raised as to ownership of an invention or patents under these provisions, the matter shall be referred to a committee of five members to be named by the chancellor of State University. At least three of such members shall be members of the academic staff of the university. Such committee shall make a careful investigation of the circumstances under which the invention was made and shall transmit its findings and conclusions to the chancellor for review. If the committee determines that the invention has been made without the use of university facilities and not in the course of the inventor's employment by or for the university, and the chancellor concurs in such determination, the university will assert no claim to the invention or to any patents obtained thereon."

THE HEARING BY THE AD HOC COMMITTEE APPOINTED BY THE CHANCELLOR

A hearing was held on February 28, 2005 in the Matter of the Research Foundation and the petitioner in accordance with SUNY Patents Policy as set forth above. The Interim Chancellor named the following Committee members who made the recommendations based upon the consensus and agreement of the entire Committee: Dr. Deborah Duen Ling Chung, University of Buffalo; Dr. Anne E. Huot, Executive Vice Provost, Office of Academic Affairs, State University Plaza; Dr. Albert J.T. Mills, University of Albany/SUNY; Dr. R.N. Miles, State University of New York at Binghamton; and Ajit J. Vaidya, Esq., Hogan & Hartson, LLP, Washington, D.C. Findings, recommendations and conclusions were then provided by the Ad Hoc Committee to the Chancellor for review and consideration after proper inquiry to determine the issue of whether SUNY facilities were used by the petitioner relating to the claims and thus whether the petitioner was co-owner of the inventions at issue.

After conducting the hearing and considering the extensive evidentiary submissions, and testimonies presented by all parties, the Ad Hoc Committee recommended that:

(1) The petitioner remain a co-owner of U.S. Patents Application Serial#10/369,100 (the 100 application) and the patents that issued based upon that application; that the 100 application was currently limited to 21 patent claims (originally filed claims 1-19, 46 and 47); that the remaining claims had been cancelled in response to Restriction Requirement issued by the U.S. Patents & Trademark Office; and therefore, the petitioner was not required to assign to the Research Foundation his rights in claims 1-19 and 46 and 47. The Ad Hoc Committee did not find that animal testing was required in order to support the originally filed claims 1-19, and 46 and 47. The Ad Hoc Committee further did not find that the invention of claims 1-19, and 46 and 47 qualified as "inventions made by faculty members, employees, students, and all others utilizing university facilities at any of the State-operated institutions of State University," which would require that such inventions "belong to State University..." or that the invention of claims 1-19, 46 and 47 was made in the course of the inventor's employment by or for the university";

(2) The petitioner was required to assign his rights in claims 20-45 and 48-51 that were originally filed in the 100 application, but later cancelled in response to the Restriction Requirement; and that the Ad Hoc Committee understood that those claims might be re-filed in a divisional patent application. The Ad Hoc Committee recommended that the petitioner's interest in such divisional application and corresponding issued patent(s) be assigned to the Research Foundation. The Ad Hoc Committee stated that the recommendations as to claims 20-45 and 48-51 were made because animal testing was required to support these patent claims. Since the petitioner conducted animal testing using a SUNY laboratory for claims 20-45 and 48-51 and because those patent claims relied upon the tests, they should be assigned to the Research Foundation under the strict standards imposed by the State Title 8, Chapter V, Subchapter B, §335.29 of the Official Compilation of Codes, Rules and Regulations.

The Ad Hoc Committee added that it had not been asked to investigate who, in addition to the petitioner, should be named as the inventor of claims 1-19 and 46 and 47 and who in addition to the petitioner owned the 100 application. The Ad Hoc Committee took into account in its recommendations and conclusions the various submissions including those from the Research Foundation.

(3) Finally, the Ad Hoc Committee recommended that the Research Foundation revisit the current policy on inventions (State Title 8, Chapter V, Subchapter B, §335.28 of the Official Compilation of Codes, Rules and Regulations as provided in a separate addendum to the Statement). In its addendum, the Ad Hoc Committee strongly urged that the SUNY consider revising the current policy on inventions approved on September 19, 1979 and amended on November 16, 1988, as since that time, SUNY research and development activities had greatly expanded and there had been a significant growth in private sector business, including companies that were formed within SUNY operated incubators. Various arrangements with private sector businesses were generally encouraged because of their potential to rapidly commercialize new technologies, as well as their potential to create new jobs within the community. The Ad Hoc Committee stated that an inventions policy that may be perceived as unclear and that may lead to confusion over the ownership of developed technologies might discourage private sector investment. A policy viewed as both clear and equitable would encourage SUNY faculty to expand the scope of research.

CHANCELLOR REJECTS THE AD HOC COMMITTEE'S FINDINGS AND RECOMMENDATIONS

The petitioner claims that Timothy P. Murphy, the Vice President and Chief Operating Officer of the Research Foundation and a subsequent member of the Patents Board, urged the Chancellor to reject the Ad Hoc Committee's recommendations arguing that the SUNY and Research Foundation patent policies did not contain a *de minimis* use exception; and the fact that the disputed intellectual property was developed at Brook Bio was irrelevant insofar as the SUNY facilities were used for the parent patents. The Ad Hoc Committee findings and recommendations were then rejected by the Chancellor.

CONCLUSION

The Court finds, as a matter of law, that the Chancellor's rejection of the findings and recommendations made by the Ad Hoc Committee appointed by the Interim Chancellor is without a

rational basis, is arbitrary and capricious, and unsupported by substantial evidence and the record as a whole.

In the Matter of Edwin A. Pell, Jr. v Board of Education of Union Free School District No. 1 of the Town of Scarsdale and, et al, 34 NY2d 222, 356 NYS2d 833 [1974], the Court found at 839, "In Article 78 proceeding ... that neither the Appellate Division nor the Court of Appeals has power to upset the determination of an administrative tribunal on a question of fact; ... the courts have no right to review the facts generally as to weight of evidence, beyond seeing to it that there is 'substantial evidence'...." The courts cannot interfere unless there is no rational basis for the exercise of discretion or the action complained of is 'arbitrary and capricious'... The arbitrary or capricious test chiefly 'relates to whether a particular action should have been taken or is justified... and whether the administrative action is without foundation in fact'. Arbitrary action is without sound basis in reason and is generally taken without regard to the facts. ... The proper test is whether there is a rational basis for the administrative orders, *the review not being of determination made after quasi-judicial hearings required by statute or law*. Where, however, a hearing is held, the determination must be supported by substantial evidence, CPLR 7803(4); And where a determination is made and the person acting has not acted in excess of his jurisdiction, in violation of lawful procedure, arbitrarily, or in abuse of his discretionary power, including discretion as to the penalty imposed, the courts have no alternative but to confirm his determination, CPLR 7803(3). Rationality is what is reviewed under both the substantial evidence rule and the arbitrary and capricious standard...." and at 840 "A court may not substitute its judgment for that of the board or body it reviews unless the decision under review is arbitrary and unreasonable and constitutes an abuse of discretion."

As stated in ***Gramatan Avenue Associates v State Division of Human Rights***, 45 NY2d 176, 408 NYS2d 54 [1978], "generally speaking, upon a judicial review of findings made by an administrative agency, a determination is regarded as being supported by substantial evidence when the proof is so substantial that from it an inference of the existence of the fact found may be drawn reasonably.... The concept of substantial evidence, a term of art as related to administrative decision making, is rather easily verbalized, but, when put to use in respect to a particular determination, frequently causes difficulty and disagreement. It is related to the charge or controversy and involves a weighing of the quality and quantity of the proof Essential attributes are relevance and a probative character. Marked by its substance, its solid nature and ability to inspire confidence, substantial evidence does not rise from bare surmise, conjecture, speculation, or rumor. More than seeming or imaginary, it is less than a preponderance of the evidence, overwhelming evidence, or evidence beyond a reasonable doubt.... Whether an administrative agency determination is shored up by substantial evidence is a question of law to be decided by the courts, it having been stated with some frequency that insufficient evidence is, in the eyes of the law, no evidence.... The reviewing court should review the whole record to determine whether there is a rational basis set forth in its findings of fact supporting the agency's decision."

A review of the entire record in this case establishes that the CIP application for chimeric proteins did not require the use of animal testing and such animal testing was not conducted with regard to the disputed 100 application limited to 21 patents claims i.e. originally filed claims 1-19, 46 and 47; of which the remaining claims were cancelled in response to a Restriction Requirement issued by the U.S. Patents & Trademark Office; and that therefore, the petitioner is not required to assign to the Research Foundation his rights in claims 1-19 and 46 and 47. The Ad Hoc

Committee determined that animal testing was not required in order to support the originally filed claims 1-19, and 46 and 47. The Research Foundation submitted no evidence, let alone substantial evidence to the contrary, to support its claim that animal testing was indeed conducted for the originally filed claims 1-19 and 46 and 47. Nor was there any evidence submitted other than conclusory assertions that the petitioner's invention of the patent claims 1-19, 46 and 47 was made in the course of his employment by or for SUNY.

SUNY counsels D. Andrew Edwards Jr. and Lisa A. Alexander, in a letter, dated February 2, 2006, to Chancellor John R. Ryan stated that the Research Foundation submitted to the Ad Hoc Committee on February 28, 2005 affirmations signed by Dattwyler, Gomes-Solecki and Laura Hannafey, which affirmations the Research Foundation relied upon to demonstrate that animal testing was conducted at the SUNY laboratory.

Dattwyler's affirmation to the Ad Hoc Committee, in support of SUNY's position, stated that he was President of Brook Bio as well as a SUNY employee and that Brook Bio had never been capable of performing animal studies in its laboratory nor had it ever performed such animal studies. He stated that the immunization and histogram data of Exhibits 2, 6, and 8 attached to his affirmation (but not included with Exhibit 14 of the affirmation of Heather M. Hage, Esq.) were based upon animal studies that could not have been done at or on behalf of Brook Bio.

Gomes-Solecki's affirmation to the Ad Hoc Committee, in support of SUNY's position, stated that she worked full time as a scientist at Brook Bio, and that Brook Bio had never been capable of performing animal studies in its laboratory and did not contract for any animal studies on its behalf, and therefore it was impossible that any immunization, vaccination or histogram data could have been gathered without laboratory work being done outside Brook Bio.

Laura Hannafey's affirmation to the Ad Hoc Committee, in support of SUNY's position, stated that she worked full-time as a technician at Brook Bio and that it had never been capable of performing animal studies, nor did it do any in its laboratory. Further, it was impossible that any immunization, vaccination or histogram data had been gathered with laboratory work outside of Brook Bio.

The aforementioned affirmations submitted by Dattwyler, Gomes-Solecki, and Laura Hannafey, considered and relied upon by the respondents in their claim, are not dispositive as they do not demonstrate that any of the animal research performed at the SUNY laboratory was related to claims 1-19, 46 and 47. Further, the Ad Hoc Committee found that the specific 1-19, 46 and 47 did not require animal testing. Christopher Hanifin, Esq., Deputy Counsel for the Research Foundation sent a memo, dated March 11, 2005, to Lisa Alexander, Esq. of the SUNY Counsel office containing various questions concerning information requested by the Ad Hoc Committee relative to the Ad Hoc Committee's investigation and recommendations. As noted in the response to the memo, dated June 2, 2005, the Research Foundation responded to number 5, in part, that "claims 1-19 did not need animal testing for support." Therefore, the Chancellor and Research Foundation were aware that those items in the CIP, as set forth in the recommendations by the Ad Hoc Committee, did not require animal testing.

Sheldon Halpern, Chairman Ad Hoc of the Patents Board (hereinafter Halpern) wrote to the Chancellor, advising that on June 21, 2006, SUNY Counsel and Vice Chancellor Nicholas Rostow formally asked the Patents Board, on the Chancellor's behalf, to review the complete file of the petitioner and make recommendations to the Chancellor with respect to its disposition. A meeting, called by the Patents Board, was held on August 4, 2006 and the petitioner, who was not permitted to have legal counsel represent him, was given one half-hour for his presentation concerning the Patents Board's response to the Ad Hoc Committee's recommendations and the Patents Board's review of the petitioner's file. Halpern stated in his letter that in accordance with SUNY policies governing a question raised as to rights to a patent or invention, the predecessor Interim Chancellor appointed an Ad Hoc Committee to conduct an investigation and to recommend a course of action to the Chancellor after making "careful investigation of the circumstances under which the invention was made and shall transmit its findings and conclusions to the Chancellor for review. If the Ad Hoc Committee determines that the invention has been made without the use of the University facilities and not in the course of the inventor's employment by or for the University and the Chancellor concurs in such a determination, the University will assert no claim to the Invention or to any patents obtained thereon."

Here the Court finds that the disputed claims 1-19, 46 and 47 were made without the use of SUNY facilities and not in the course of the petitioner's employment by or for SUNY, and did not require animal testing.

Halpern further stated at page 5 of his letter that at some time in 2005, the U.S. Patents and Trademark Office divided the CIP application in two parts (because it determined that the patents application covered more than one invention, and a divisional application needed to be filed during the life of the parent application). Halpern also stated "If such an application has not been filed, it should be." As one of the members of the Ad Hoc Committee explained to the Patents Board on September 15, 2006, this division became the basis for the conclusion by the Ad Hoc Committee that ownership of the patent should be split as well. Ajit J. Valdyia, Esq. a member of that Ad Hoc Committee, stated that he knew what research required animal testing and what did not, and that those claims hived off⁴ by the U.S. Patents and Trademark Office did not require animal testing.

Based upon the foregoing, the Ad Hoc Committee rejected the Research Foundation's claims and determined that those claims hived off by the U.S. Patent and Trademark Office did not require animal testing and that part of the petitioner's work was not based upon animal testing at the SUNY laboratory. The Research Foundation's claim that animal testing was done at the SUNY laboratory is not supported by the record. The respondent's have not demonstrated that any animal testing was involved in the research for the chimeric proteins described in the CIP claims 1-19, 46 and 47. What has been demonstrated are two patent applications and two inventions. What has been ignored is the finding by the Ad Hoc Committee that animal testing was not required for the CIP application and thus there was no use of the SUNY laboratory for the chimeric inventions hived off by the U.S. Patents and Trademark Office. Without such animal testing, the respondents' argument that SUNY laboratory facilities were used for testing relative to the CIP application cannot be sustained.

⁴Removed from the group, (as quoted from Ajit J. Valdyia, Esq. in the Ad Hoc Committee determination).

In applying the provisions of the SUNY Patents and Inventions Policy, as set forth above, the petitioner by Brook Bio has clearly established by the evidence submitted that he retained ownership of claims 1-29, 46 and 47 as the inventions were made by an individual wholly on such individual's own time, and without the use of SUNY facilities, and as such they belong to the petitioner even though they fall within the field of competence relating to the petitioner's SUNY position. The respondents have submitted no evidence to demonstrate that such invention was made other than on the petitioner's own time without the use of SUNY facilities.

The respondents claim that the provisions of the SUNY Patents and Inventions Policy do not provide for "*de minimus*" use exception and the policy does not provide only for "required use" of the SUNY facilities (not the actual use of such facilities). However, assuming the policy could be so construed, substantial evidence and the totality of the record demonstrate that the chimeric proteins described in the CIP were not part of the original grant, but were new polypeptides which were developed and were not described in the initial patents, including the development of OspC chimeric proteins comprised of polypeptide derived from different OspC homologs and polypeptides comprised of two outer surface proteins, OspC and OspA which required no animal testing. Therefore, there is no rational basis to rely on a "*de minimus*" use exception or "required use" of SUNY facilities for this separate invention.

SUBMIT JUDGMENT



J.S.C.