COOLEY GODWARD KRONISH LLP
STEPHEN C. NEAL (No. 170085) (nealsc@cooley.com)
RICARDO RODRIGUEZ (No. 173003) (rr@cooley.com)
MICHELLE S. RHYU (No. 212922) (mrhyu@cooley.com)
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
Tel: (650) 843-5000
Fax: (650) 857-0663

Attorneys for Plaintiff and Counterclaim Defendant
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY
and Counterclaim Defendants THOMAS MERIGAN and MARK HOLODNIY

PRUETZ LAW GROUP LLP
Adrian M. Pruetz (Bar No. 118215) (ampruetz@pruetzlaw.com)
1600 Rosecrans Avenue, 4th Floor
Manhattan Beach, CA 90266
Tel: (310) 321-7640
Fax: (310) 321-7641

QUINN EMANUEL URQUHART OLIVER & HEDGES LLP
Brian C. Cannon (Bar No. 193071) (briancannon@quinnemanuel.com)
Tun-Jen Chiang (Bar No. 235165) (tjchiang@quinnemanuel.com)
555 Twin Dolphin Drive, Suite 560
Redwood Shores, CA 94065
Tel: (650) 801-5000
Fax: (650) 801-5100

Attorneys for Defendants and Counterclaimants ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; and ROCHE DIAGNOSTICS OPERATIONS, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Defendants.

Case No. C 05 04158 MHP

**JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT UNDER PATENT LOCAL RULE 4-3**

Hon. Marilyn Hall Patel

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY; THOMAS MERIGAN; AND MARK HOLODNIY,

Counterclaim Defendants.

Pursuant to the Court's June 1, 2007, Order Re Case Management (Docket No. 161) and Patent Local Rule 4-3, Plaintiff and Counterclaim Defendant The Board of Trustees of the Leland Stanford Junior University ("Stanford") and Defendants and Counterclaimants Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc. (collectively, "Roche") hereby submit this Joint Claim Construction and Prehearing Statement.

## I. CONSTRUCTION OF CLAIM TERMS ON WHICH THE PARTIES AGREE (RULE 4-3(A))

| Terms | Joint Construction |
|---|---|
| "plasma sample" | "a sample of the liquid part of the blood" |

## II. CONSTRUCTIONS OF DISPUTED CLAIM TERMS AND IDENTIFICATION OF INTRINSIC AND EXTRINSIC EVIDENCE (RULE 4-3(B))

The figure below lists each party's proposed constructions for the disputed claim terms. Stanford asserts that no construction is necessary for many of the terms identified by Roche and, therefore, reserves the right to object to Roche's proposed constructions on that basis. In the chart attached as Exhibit A, Stanford identifies intrinsic and extrinsic evidence upon which it may rely to support its claim constructions or oppose Roche's constructions. In the chart attached as Exhibit B, Roche identifies intrinsic and extrinsic evidence upon which it may rely to support its claim constructions or oppose Stanford's constructions.

| Terms | Stanford's Construction | Roche's Construction |
|---|---|---|
| "evaluating the effectiveness of anti-HIV therapy of a patient" and "evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient" | No construction necessary. Alternatively, "examining whether a treatment of a patient has the ability to provide therapeutic benefits with regard to an HIV infection" | "medical decision as to whether anti-HIV therapy is having the intended effect and whether treatment should be modified" |

| Terms | Stanford's Construction | Roche's Construction |
|---|---|---|
| "evaluating the effectiveness" | No separate construction necessary. Alternatively, see *supra* "evaluating the effectiveness of anti-HIV therapy of a patient" and "evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient" | "medical decision as to whether anti-HIV therapy is having the intended effect and whether treatment should be modified" |
| "an antiretroviral agent" | "at least one substance having, capable of having, or intended to have an effect against a retrovirus, such as HIV" | "antiretroviral agents available to doctors for the treatment of AIDS/HIV infected patients in 1992" |
| "about 30 cycles" | No construction necessary. Alternatively, "approximately 30 cycles" | "29 to 31 cycles of PCR" |
| "correlates positively" | "renders the conclusion (or result) more likely than other conclusions (or results)" | "a particular result renders a particular conclusion more likely than other conclusions" |
| "therapeutically effective" | No construction necessary. Alternatively, "providing therapeutic benefits" | "elicits the medical effect intended by the treating physician such that the course of treatment is not modified" |
| "therapeutically ineffective" | No construction necessary. Alternatively, "not providing therapeutic benefits" | "fails to elicit the medical effect intended by the treating physician as a result of drug resistance such that the course of treatment is modified" |
| "SK38" | No construction necessary because the term "SK38" is not present in any of the asserted claims. Alternatively, "5'-ATA ATC CAC CTA TCC CAG TAG GAG AAAT" | "HIV primer for PCR developed by Cetus scientist Shirley Kwok having the sequence 5'-ATA ATC CAC CTA TCC CAG TAG GAG AAAT" |
| "SK39" | No construction necessary because the term "SK39" is not present in any of the asserted claims. Alternatively, "5'-TTT GGT CCT TGT CTT ATG TCC AGA ATG C" | "HIV primer for PCR developed by Cetus scientist Shirley Kwok having the sequence 5'-TTT GGT CCT TGT CTT ATG TCC AGA ATG C" |

| Terms | Stanford's Construction | Roche's Construction |
|---|---|---|
| "conclusion" | No construction necessary. Alternatively, "a judgment or decision reached after deliberation." | "medical diagnosis for a particular patient" |
| "presence of detectable HIV-encoding nucleic acid" | No construction necessary. Alternatively, "the existence or occurrence of HIV-encoding nucleic acid above the lower level of sensitivity of the quantitative PCR assay" | "qualitative result indicating greater than 40 copies of HIV RNA per ml" |
| "absence of detectable HIV-encoding nucleic acid" | No construction necessary. Alternatively, "the non-existence of HIV-encoding nucleic acid above the lower level of sensitivity of the quantitative PCR assay" | "qualitative result indicating less than 40 copies of HIV RNA per ml" |
| "measuring the HIV RNA copy number" | No construction necessary. Alternatively, "estimating the number of copies of an HIV RNA sequence by evaluation" | "techniques available in May 1992 to quantify HIV RNA copy number using PCR, specifically the assay in the 1991 JID article as set forth in the specification" |
| "collecting statistically significant data useful for determining whether a decline in HIV RNA copy numbers exists" | "gathering data from the patient and/or other sources that is useful in assessing whether any decline in HIV RNA copy number was the result of chance" | "collecting statistically significant data upon which a physician should rely in order to make a medical diagnosis about a patient" |
| "statistically significant data" | No separate construction necessary. Alternatively, see *supra* "collecting statistically significant data useful for determining whether a decline in HIV RNA copy numbers exists" | "the probability that the relationship between data is not due to chance. The patent specification does not define any probability value for this data" |
| "statistically significant decline" | "a decrease that is large enough, by itself or when compared to other data, that it was not likely the result of chance" | "data upon which a physician should rely in order to make a medical diagnosis about decline of HIV. The patent specification does not define any probability value for this data" |

| Terms | Stanford's Construction | Roche's Construction |
|---|---|---|
| "The method of claim 7" | "The method of claim 8" | This term does not require construction |
| "correlating" | "establishing a mutual relationship between" | "the relationship in a patient between viral load and a particular condition" |

## III. ANTICIPATED LENGTH OF TIME FOR CLAIM CONSTRUCTION HEARING (RULE 4-3(C))

The claim construction hearing is scheduled for October 3, 2007. The parties propose two hours in the morning for a technology tutorial and three hours in the afternoon for oral argument, with equal time for each side.

## IV. IDENTIFICATION OF WITNESSES AND SUMMARY OF TESTIMONY (RULE 4-3(D))

Although Stanford does not contend or concede that expert testimony is necessary, Stanford, if permitted by the Court, may present a tutorial by Dr. Paul Volberding and/or Dr. Fred Kramer, as well as offer expert testimony from these witnesses in support of Stanford's constructions of the claim terms or in opposition to Roche's constructions. Additionally, at the time Stanford files its claim construction briefs, it may submit supporting declarations of Dr. Volberding and/or Dr. Kramer. Dr. Volberding is a Professor of Medicine and the Director of the Center for AIDS Research at the University of California, San Francisco, and Director of the AIDS Program and Medical Oncology at San Francisco General Hospital. Dr. Kramer is a Member and Chairman of the Department of Molecular Genetics and Director of the Office of Technology Transfer of The Public Health Research Institute, an Adjunct Professor in the Department of Microbiology in the New York University School of Medicine, and a Professor of Microbiology and Molecular Genetics at New Jersey Medical School in the University of Medicine and Dentistry of New Jersey. The resumes for Dr. Volberding and Dr. Kramer are attached as Exhibit C. A summary of the opinions to be offered by Dr. Volberding and Dr. Kramer is attached as Exhibit D in accordance with Patent Local Rule 4-3(d). Stanford objects to Roche's inclusion of Dr. Jeffrey Lifson in this disclosure because Dr. Lifson was not included in Roche's Patent Local Rule 4-2 disclosure.

Roche, if permitted by the Court, may present a tutorial by Dr. John G. Bartlett and Dr. Jeffrey D. Lifson, as well as offer expert testimony from these witnesses in support of Roche's constructions of the claim terms or in opposition to Stanford's constructions. Both of these experts were identified in Roche's Amended Preliminary Claim Construction And Extrinsic Evidence Pursuant to Patent Local Rule 4-2 served July 3, 2007. Additionally, at the time Roche files its claim construction brief, it may submit a supporting declaration by Dr. Bartlett and/or Dr. Lifson. Dr. Bartlett is Professor of Medicine at Johns Hopkins University School of Medicine, Chief of AIDS Service at Johns Hopkins, and the former Chief of the Division of Infectious Disease at Johns Hopkins. Dr. Bartlett is expected to provide a background tutorial explaining basic medical and biological concepts, including the transmission and progression of HIV infection, the immune reaction of the body, including the role of CD4 cells, and the treatment of HIV infected patients, as well as any other medical matter the Court may ask the parties to comment upon at or for the claim construction hearing. Dr. Bartlett's resume is attached as Exhibit E. Dr. Lifson is the Director of the AIDS Vaccine Program and is also Senior Principal Scientist and Head of the Retroviral Pathogenesis Laboratory at the National Cancer Institute in Frederick, Maryland. He may provide a technical tutorial on quantitative PCR techniques. Dr. Lifson's resume is attached as Exhibit F. The foregoing tutorials are not intended to be "opinion" admissible as evidence for purposes of claim construction.

A summary of the expert opinions to be offered by Drs. Bartlett and Lifson is attached as Exhibit G in accordance with Patent Local Rule 4-3(d).

## V. ISSUES FOR PREHEARING CONFERENCE (RULE 4-3(E))

At the prehearing conference, the parties would like to address the logistics for a technology tutorial and procedures for claim construction-related witness testimony. The parties have discussed foregoing depositions of claim construction experts. Roche is willing to forgo depositions so long as Stanford's witnesses attend the October 3, 2007, claim construction hearing and are subject to cross-examination at that time. Stanford considers live testimony and cross-examination unnecessary.

Dated: July 6, 2007

COOLEY GODWARD KRONISH LLP

by: /s/
Ricardo Rodriguez

Attorneys for Plaintiff and Counterclaim Defendant The Board of Trustees of the Leland Stanford Junior University and Counterclaim Defendants Thomas Merigan and Mark Holodniy

Dated: July 6, 2007

QUINN EMANUEL URQUHART OLIVER & HEDGES LLP

by: /s/
Brian C. Cannon

Attorneys for Defendants and Counterclaimants Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc.

/s/
Ricardo Rodriguez

Filer's Attestation: Pursuant to General Order No. 45, Section X(B) regarding signatures, I hereby attest that concurrence in the filing of the document has been obtained.