

Exhibit 30

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THE BOARD OF TRUSTEES OF THE LELAND STANFORD
JUNIOR UNIVERSITY and Counterclaim Defendant THOMAS
MERIGAN

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.

ROCHE MOLECULAR SYSTEMS, ET AL.,

Counterclaimants,

v.

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

Counterclaim Defendants.

Case No. C 05 04158 MHP

**STANFORD UNIVERSITY'S DISCLOSURE
OF ASSERTED CLAIMS AND
PRELIMINARY INFRINGEMENT
CONTENTIONS AND DOCUMENT
PRODUCTION ACCOMPANYING
DISCLOSURE**

Pursuant to Patent Local Rules 3-1 and 3-2 plaintiff The Board of Trustees of the Leland Stanford Junior University ("Stanford") provides this Disclosure of Asserted Claims and Preliminary Infringement Contentions and Document Production Accompanying Disclosure ("Disclosure").

This Disclosure is based upon the best information currently available to Stanford. At the present time, Stanford may not have received from Roche Molecular Systems, Inc., Roche Diagnostics Corporation and Roche Diagnostics Operations, Inc., (collectively, "Roche") all the information that may be relevant relating to Roche's products. Discovery is ongoing. Accordingly, Stanford expressly reserves its right to amend or modify this Disclosure as information on Roche's products is discovered, and as contemplated by Patent Local Rules 3-6 and 3-7 and F.R.C.P. 26(e).

I. PATENT L.R. 3-1(A) DISCLOSURE

Defendants have infringed and continue to infringe at least claims 1, 5-9, 13-14, 18-19, and 23 of U.S. Patent 5,968,730 ("730 patent") and claims 1 and 5-10 of U.S. Patent 6,503,705 ("705 patent"), as shown in Table A.

II. PATENT L.R. 3-1(B) DISCLOSURE

Roche's sale of the Amplicor HIV-1 Monitor Test in conjunction with the instructions and anticipated used, including the FDA product label and package insert, are the basis for Stanford's charge of infringement for each asserted claim. These documents are included in the accompanying production at STAN 007412- STAN 007672.

III. PATENT L.R. 3-1(C) DISCLOSURE

Attached as Table A are Stanford's claim charts for the asserted claims of the '730 and '705 patents.

IV. PATENT L.R. 3-1(D) DISCLOSURE

Roche infringes each element of each asserted claim literally and under the doctrine of equivalents.

V. **PATENT L.R. 3-1(E) DISCLOSURE**

Stanford claims priority to the 07/883,327 application filed on May 14, 1992 for the '730 and '705 patents.

VI. **PATENT L.R. 3-1(F) DISCLOSURE**

Stanford does not intend to rely on its own apparatus, product, device, process, method, act or other instrumentality as evidence in this action.

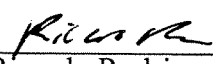
VII. **PATENT L.R. 3-2 DISCLOSURE**

Stanford has produced all documents required by Patent Local Rule 3-2 that are currently available. Stanford reserves the right to supplement this Disclosure as other documents become available and/or are identified.

CATEGORY	BATES NUMBERS
Rule 3-2(a)	STAN 000840 – STAN 000845
Rule 3-2(b)	STAN 003275 – STAN 003680; STAN 005421- STAN 005517; STAN 005257 – STAN 005420; STAN 005766 – STAN 005854; STAN 004761 – STAN 004895; STAN 000840 – STAN 000845
Rule 3-2(c)	STAN 000001 – STAN 001472; STAN 006046 – STAN 007411

Dated: February 28, 2006

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By: 
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THE BOARD OF TRUSTEES OF LELAND
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TABLE A TO STANFORD'S DISCLOSURE OF ASSERTED CLAIMS AND PRELIMINARY INFRINGEMENT CONTENTIONS

U.S. PATENT 5,968,730

Limitations of the '730 Patent	Amplicor HIV-1 Monitor Test
Claim 1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising (i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent; (ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and (iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR; in which the absence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically effective.	The Amplicor test is intended for use in monitoring the effects of antiretroviral therapy. (STAN 007454.) In the Amplicor testing procedure, HIV-1 RNA is obtained from a plasma sample. (STAN 00007455-56.) The Amplicor testing procedure specifies the use of 30 cycles for amplification using PCR. (STAN 007472.) The Amplicor testing procedure obtains quantitative detection of HIV-1 viral RNA, thereby revealing the presence of HIV encoding nucleic acids in the plasma sample. (STAN 007455.) The Amplicor testing procedure is stated to be validated for the monitoring of the effect of antiretroviral therapy by serial measurement of plasma HIV-1 RNA. Thus, the Amplicor testing procedure includes instances in which serial tests show the absence of detectable HIV-1 RNA as compared to a prior test showing substantial numbers of HIV-1 RNA. (STAN 007454.) Zidovudine is AZT, one of the most commonly used antiretroviral agents. AZT is one of the referenced antiretroviral agents in the Amplicor product label. (STAN 007488.)
Claim 5. The method of claim 1, 2, 3 or 4 in which the antiretroviral agent is zidovudine.	See claim 1.
Claim 6. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising (i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	See claim 1.

Limitations of the '730 Patent	Amplicor HIV-1 Monitor Test
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	See claim 1.
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	See claim 1.
in which the presence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective.	The Amplicor testing procedure is stated to be validated for the monitoring of the effect of antiretroviral therapy by serial measurement of plasma HIV-1 RNA for patients. (STAN 007454.) For patients whose copy number becomes undetectable, the presence of HIV-1 RNA on a subsequent test would correlate positively with the conclusion that the antiretroviral agent has become therapeutically ineffective.
Claim 7. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	See claim 1.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	See claim 1.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	See claim 1.
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	See claim 1.
in which the presence of detectable HIV-encoding nucleic acid correlates positively with an absolute CD4 count of less than 200 cells per cubic millimeter.	CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The Amplicor label refers to CD4 count throughout, and CD4 count was a part of the clinical studies cited in the Amplicor label.
Claim 8. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	See claim 1.

Limitations of the '730 Patent	Amplicor HIV-1 Monitor Test
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	See claim 1.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	See claim 1.
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	See claim 1.
in which the absence of detectable HIV-encoding nucleic acid correlates positively with an absolute CD4 count of greater than 200 cells per cubic millimeter.	CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The Amplicor label refers to CD4 count throughout, and CD4 count was a part of the clinical studies cited in the Amplicor label.
Claim 9. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	See claim 1.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	See claim 1.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	See claim 1.
(iii) measuring the HIV RNA copy number using the product of the PCR, in which an HIV RNA copy number greater than about 500 per 200 ul of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective.	The Amplicor Label identifies various changes in copy number that correlates to the effectiveness of anti-HIV therapy. (STAN 007488-502.) For example, a 5 fold increase is identified as providing information on the effectiveness of anti-HIV therapy. (Id.) A 5 fold increase that results in a copy number greater than about 500 per 200 ul of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective. (Id.)
Claim 13. The method of claim 9, 10, 11 or 12 in which the antiretroviral agent is zidovudine.	See claim 5.

Limitations of the '730 Patent	Amplicor HIV-1 Monitor Test
Claim 14. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	See claim 1.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	See claim 1.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	See claim 1.
(iii) measuring the HIV RNA copy number using the product of the PCR, in which an HIV RNA copy number less than about 200 per 200 ul of plasma correlates positively with the conclusion that the anti-HIV agent is therapeutically effective.	See claim 6. The same analysis applies, but for a copy number of 200 instead of 500 per 200 ul of plasma.
Claim 18. The method of claim 14, 15, 16 or 17 in which the antiretroviral agent is zidovudine.	See claim 5.
Claim 19. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	See claim 1.
(i) collecting one pre-treatment plasma sample from an HIV-infected patient who is about to be treated with an antiretroviral agent;	The Amplicor kit is intended for use in monitoring the effectiveness of antiretroviral treatment, and does not limit its use to only patients who have already begun treatment. (STAN 007454.)
(ii) collecting a post-treatment plasma sample from the HIV-infected patient after the patient has been treated with the antiretroviral agent;	The Amplicor kit is intended for use in monitoring the effectiveness of antiretroviral treatment wherein HIV RNA levels are measured over the course of treatment. (STAN 007454.)

Limitations of the '730 Patent	Amplicor HIV-1 Monitor Test
(iii) amplifying the HIV-encoding nucleic acid in the pre-treatment and post-treatment plasma samples using HIV primers in about 30 cycles of PCR;	See claim 1.
(iv) measuring the HIV RNA copy number using the products of the PCRs of step (iii); and	The Amplicor test measures the copy number of HIV-1 RNA. (STAN 007454.)
(v) comparing the HIV RNA copy number in pre-treatment and post-treatment plasma samples,	The Amplicor test is intended for use in monitoring the effects of antiretroviral therapy by comparing changes in HIV-1 RNA over the course of treatment. (STAN 007454.)
in which a ratio of HIV RNA copy number in pre-treatment and post-treatment plasma samples of greater than about 4 to 1 correlates positively with the conclusion that the anti-HIV agent is therapeutically effective.	The Amplicor Label identifies various circumstances in which changes in copy number correlate to the effectiveness of anti-HIV therapy by providing an indication of disease progression for patients on anti-HIV therapy. (STAN 007488-502.)
Claim 23. The method of claim 19, 20, 21 or 22 in which the antiretroviral agent is zidovudine.	See claim 5.

U.S. PATENT 6,503,705

<u>Limitations of the '705 Patent</u>	<u>Amplicor HIV-1 Monitor Test</u>
1. A method of evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient comprising:	The Amplicor test is intended for use in monitoring the effects of antiretroviral therapy. (STAN 007454.)
a) collecting statistically significant data useful for determining whether or not a decline in plasma HIV RNA copy number exists after initiating treatment of an HIV-infected patient with an antiretroviral agent by:	See the claim limitations that follow.
(i) collecting more than one plasma sample from the HIV-infected patient at time intervals sufficient to ascertain the existence of a statistically significant decline in plasma HIV RNA copy numbers;	In the Amplicor testing procedure, HIV-1 RNA is obtained from a plasma sample. (STAN 007455-56.) The Amplicor testing procedure is stated to be validated for monitoring of the effects of antiretroviral therapy by serial measurement. (STAN 007454.) The sensitivity of the Amplicor test allows for the measurement of statistically significant changes. (STAN 007486-87.)
(ii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;	The Amplicor testing procedure specifies the use of 30 cycles for amplification using PCR. (STAN 007472.)
(iii) measuring HIV RNA copy numbers using the products of the PCR of step (ii);	See claim 19 of the '730 patent.
(iv) comparing the HIV RNA copy numbers in the plasma samples collected during the treatment; and	See claim 19 of the '730 patent.
b) evaluating whether a statistically significant decline in plasma HIV RNA copy numbers exists in evaluating the effectiveness of anti-HIV therapy of a patient.	The Amplicor Label discusses the significance of the effect of various different types of changes in the measured copy number, in connection with the effectiveness of the anti-HIV therapy. (STAN 007488-502.)
5. The method of claim 1 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. AZT is one of the referenced antiretroviral agents in the Amplicor product label. (STAN 007488.)

<u>Limitations of the '705 Patent</u>	<u>Amplicor HIV-1 Monitor Test</u>
6. The method of claim 1, wherein the presence of a statistically significant decline in plasma HIV RNA copy number correlates positively that the antiretroviral agent is therapeutically effective.	The Amplicor Label discusses the significance of the effect of various types of changes in the measured copy number, in connection with the effectiveness of the anti-HIV therapy. (STAN 007488-502.) Copy number measurements at individual time points have statistical significance with respect to prognosis. (<i>Id.</i>)
7. The method of claim 1, wherein the absence of a statistically significant decline in plasma HIV RNA copy number correlates positively that the antiretroviral agent is therapeutically ineffective.	The Amplicor Label discusses the significance of the effect of various types of changes in the measured copy number, in connection with the effectiveness of the anti-HIV therapy. (STAN 007488-502.) Copy number measurements at individual time points have statistical significance with respect to prognosis. (<i>Id.</i>)
8. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	See claim 1.
(i) collecting a pretreatment sample from the HIV-infected patient who is about to be treated with an antiretroviral agent;	In the Amplicor testing procedure, HIV-1 RNA is obtained from a plasma sample. (STAN 007455-56.) Collection may be performed on pre-treatment patients. (STAN 007488-502.)
(ii) collecting a plasma sample after initiation of treatment with an antiretroviral agent and at a time interval sufficient to ascertain the existence of a statistically significant decline in plasma HIV RNA copy numbers;	The Amplicor testing procedure is stated to be validated for monitoring the effects of antiretroviral therapy by serial measurement. (STAN 007454.) The sensitivity of the Amplicor test allows for measurement of statistically significant changes. (STAN 007486-87.)
(iii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;	See claim 1.
(iv) measuring HIV RNA copy numbers using the products of the PCR of step (iii);	See claim 1.
(v) comparing the HIV RNA copy numbers in the plasma samples collected in the pre-treatment plasma sample and the plasma sample(s) collected after initiation of the treatment; and	See claim 1.

<u>Limitations of the '705 Patent</u>	<u>Amplicor HIV-1 Monitor Test</u>
(vi) evaluating whether a statistically significant decline in plasma HIV RNA copy number exists in evaluating the effectiveness of anti-HIV therapy of a patient.	The Amplicor Label discusses the significance of the effect of various types of changes in the measured copy number, in connection with the effectiveness of the anti-HIV therapy. (STAN 007488-502.)
9. The method of claim 8, wherein comparing the HIV RNA copy numbers of step(v) further comprises determining a ratio of HIV RNA copy numbers in the pre-treatment and the post-treatment plasma samples, wherein the ratio being greater than about 7 to 1 correlates positively with the conclusion that the antiretroviral agent is therapeutically effectiveness.	The Amplicor Label identifies various circumstances in which changes in copy number correlate to the effectiveness of anti-HIV therapy by providing an indication of disease progression for patients on anti-HIV therapy. (STAN 007488-502.)
10. The method of claim 7, wherein comparing the HIV RNA copy numbers of step(v) further comprises determining a ratio of HIV RNA copy numbers in the pre-treatment and the post-treatment plasma samples, wherein the ratio being greater than about 4 to 1 correlates positively with the conclusion that the antiretroviral agent is therapeutically effectiveness.	The Amplicor Label identifies various circumstances in which changes in copy number correlate to the effectiveness of anti-HIV therapy by providing an indication of disease progression for patients on anti-HIV therapy. (STAN 007488-502.)