Exhibit 31

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

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; THOMAS MERIGAN; AND MARK HOLODNIY,

Counterclaim Defendants.

Case No. C 05 04158 MHP

STANFORD'S SECOND AMENDED DISCLOSURE OF ASSERTED CLAIMS AND PRELIMINARY INFRINGEMENT CONTENTIONS AND SUPPLEMENTAL DOCUMENT PRODUCTION

Pursuant to Patent Local Rules 3-1 and 3-2 and the Court's Civil Pretrial Minutes (Docket No. 147), plaintiff and counterclaim defendant The Board of Trustees of the Leland Stanford Junior University ("Stanford") provides this Second Amended Disclosure of Asserted Claims and Preliminary Infringement Contentions and Supplemental Document Production ("Disclosure").

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

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"); claims 1 and 5-10 of U.S. Patent 6,503,705 ("'705 patent"); and claims 1-4 and 8 of U.S. Patent 7,129,041 ("'041 patent") as shown in Table A. Stanford asserts that Defendants have infringed and continue to infringe these claims directly, contributorily, and also by inducing others to infringe.

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

Use of each of the identified products below results in the practice of each of the claimed methods and infringement of each asserted claim.

(1) The Amplicor HIV-1 Monitor Test (original version and version 1.5; both sensitive and ultrasensitive procedures);

(2) The COBAS Amplicor HIV-1 Monitor Test (version 1.5; both sensitive and ultrasensitive procedures) with the COBAS AMPLICOR Analyzer; and

(3) The COBAS TaqMan HIV-1 Test with the COBAS TaqMan Analyzer.

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

Attached as Table A are Stanford's claim charts for the asserted claims of the '730, '705, and '041 patents.

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

As detailed in the attached Table A, Roche's manufacture, use, and sale of the Amplicor HIV-1 Monitor Test, the COBAS Amplicor HIV-1 Monitor Test with the COBAS AMPLICOR Analyzer, and the COBAS TaqMan HIV-1 Test with the COBAS TaqMan Analyzer infringe each element of each asserted claim either literally or under the doctrine of equivalents.

V. PATENT L.R. 3-1(e) DISCLOSURE

Stanford claims priority to May 14, 1992, which is the filing date of U.S. Application Serial No. 07/883,327, for all of the asserted claims of the '730, '705, and '041 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; STAN 029363 – STAN 029539

Dated: July 10, 2007

COOLEY GODWARD KRONISH LLP

by: _____
Michelle Rhyu

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

TABLE A TO STANFORD'S SECOND AMENDED DISCLOSURE OF ASSERTED CLAIMS AND PRELIMINARY INFRINGEMENT CONTENTIONS

U.S. PATENT 5,968,730

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
Claim 1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR HIV-1 MONITOR Test and the COBAS AMPLICOR HIV-1 MONITOR Test ("the AMPLICOR Tests") and the COBAS TaqMan HIV-1 Test ("the TaqMan Test") indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
	measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence of HIV-encoding nucleic acids in the plasma sample. (STAN 007457; STAN 007632; STAN 007573; STAN 031769-74.) In the AMPLICOR and TaqMan Tests, this measurement tests for the presence of HIV-encoding nucleic acid in product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 078691-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
in which the absence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically effective.	The FDA approved product labels for the AMPLICOR and TaqMan Tests state that the tests are validated for monitoring the effect of antiretroviral therapy by serial measurement of plasma HIV-1 RNA for patients. (STAN 007454; STAN 007629; STAN 007569; STAN 031769.) The AMPLICOR Test product labels and marketing materials distributed by Roche teach that,, where testing for the presence of HIV-encoding nucleic acid shows the absence of detectable HIV-encoding nucleic acid, that absence correlates positively with the conclusion that the antiretroviral agent is therapeutically effective. (STAN 007454; STAN 007569; STAN 007629; STAN 029720, STAN 029756-59; STAN 029801; RMS 0034247; RMS 078734; RMS 078824; RMS 078826; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 1.	
Claim 5. The method of claim 1, 2, 3 or 4 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 5.	
Claim 6. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence of HIV-encoding nucleic acids in the plasma sample. (STAN 007457; STAN 007632; STAN 007573; STAN 031769-74.) In the AMPLICOR and TaqMan Tests, this measurement tests for the presence of HIV-encoding nucleic acid in product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 078691-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
in which the presence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective.	The FDA approved product labels for the AMPLICOR and TaqMan Tests state that the tests are validated for monitoring the effect of antiretroviral therapy by serial measurement of plasma HIV-1 RNA for patients. (STAN 007454; STAN 007629; STAN 007569; STAN 031769.) The AMPLICOR Test product labels and marketing materials distributed by Roche teach that, where presence of detectable HIV-encoding nucleic acid is found to persist or increase with treatment, the result correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective. (STAN 007454; STAN 007569; STAN 007629; STAN 029720, STAN 029756-59; STAN 029801; RMS 0034247; RMS 078734; RMS 078824; RMS 078826; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 6.	
Claim 7. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iii) testing for the presence of HIV-encoding nucleic acid, in the product of the PCR;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence of HIV-encoding nucleic acids in the plasma sample. (STAN 007457; STAN 007632; STAN 007573; STAN 031769-74.) In the AMPLICOR and TaqMan Tests, this measurement tests for the presence of HIV-encoding nucleic acid in product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
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.	According to standard practice, CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The FDA approved product labels for the AMPLICOR Tests refer to CD4 count throughout, and the clinical studies cited in both labels correlated the presence of detectable HIV-encoding nucleic acid and CD4 counts with evaluations of the effectiveness of therapy. (STAN 007629; STAN 007658-62; STAN 007570; STAN 007617-21.) The TaqMan Test's product label also refers to CD4 count as an important indicator of patient status. (STAN 031769; STAN 031796-98.) In describing how the AMPLICOR Tests should be used, Roche's marketing materials and FDA submissions states that viral load results should be used in conjunction with CD4 counts to determine if antiretroviral therapy is effective, with effective treatment shown by the correlation of high CD4 counts with undetectable viral counts and ineffective treatment shown by low CD4 counts with detectable viral counts. (STAN 029704-21; STAN 029788-806; RMS 0014322; RMS 0014338-39; RMS 0022770; RMS 0023762; RMS 0034238-80.) Roche's web site instructs that a CD4 count of less than 200 cells per cubic millimeter is significant in determining whether an antiretroviral agent is effective. (STAN 029704-21; STAN 029788-806.) Other educational materials distributed by Roche similarly refer to CD4 counts of 200 cells/mL or less as significant. (RMS 0008621; RMS 0008623.) Roche's press release for the TaqMan Test similarly indicates that the test should be used in conjunction with other clinical markers of disease progression. (STAN 031805-08.) The TaqMan Test product label also identifies a CD4 count of less than 200 cells per cubic millimeter as an important threshold (STAN 031796-98.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 7.	
Claim 8. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iii) testing for the presence of HIV-encoding nucleic acid sequence, in the product of the PCR;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence of HIV-encoding nucleic acids in the plasma sample. (STAN 007457; STAN 007632; STAN 007573; STAN 031769-74.) In the AMPLICOR and TaqMan Tests, this measurement tests for the presence of HIV-encoding nucleic acid in product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 078691-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
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.	According to standard practice, CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The FDA approved product labels for the AMPLICOR Tests refer to CD4 count throughout, and the clinical studies cited in both labels correlated the presence of detectable HIV-encoding nucleic acid and CD4 counts with evaluations of the effectiveness of therapy. (STAN 007629; STAN 007658-62; STAN 007570; STAN 007617-21.) The TaqMan Test's product label also refers to CD4 count as an important indicator of patient status. (STAN 031769; STAN 031796-98.) In describing how the AMPLICOR Tests should be used, marketing materials distributed by Roche state that viral load results should be used in conjunction with CD4 counts to determine if antiretroviral therapy is effective, with effective treatment shown by the correlation of high CD4 counts with undetectable viral counts and ineffective treatment shown by low CD4 counts with detectable viral counts. (STAN 029704-56; STAN 029788-808; RMS 0008621-23; RMS 0014322; RMS 0014338-39; RMS 0014351; RMS 0022770; RMS 0023762; RMS 0034238-80.) Roche's web site instructs that a CD4 count of greater than 200 cells per cubic millimeter is significant in determining whether an antiretroviral agent is effective. (STAN 029704-56; STAN 029788-808.) Other educational materials distributed by Roche similarly refer to CD4 counts of 200 cells/mL or greater as significant. (RMS 0008621; RMS 0008623.) Roche's press release for the TaqMan Test similarly indicates that the test should be used in conjunction with other clinical markers of disease progression. (STAN 031805-08.) The TaqMan Test product label also identifies CD4 count of greater than 200 cells per cubic millimeter as an important threshold (STAN 031796-98.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 8.	
Claim 9. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
(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 µl of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective.	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) The product labels state that the tests measure the copy number of HIV-1 RNA. (STAN 007454; STAN 007632; STAN 007575; STAN 031769.) This measurement is performed on the product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The labels for the AMPLICOR Tests further indicate that changes in HIV RNA copy number correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18.) For example, a 5-fold change in HIV RNA copy number is identified as providing statistically significant prognostic value regarding the effectiveness of anti-HIV therapy. (STAN 007488-502.) A 5-fold increase that results in a copy number greater than about 500 per 200 µl of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective. Furthermore, with respect to the AMPLICOR Tests, Roche teaches that, when evaluating whether a change in HIV RNA from undetectable levels to detectable levels is meaningful, physicians should look for a 6-fold change from the test's lower limit of 400 copies/mL, which is a change to above 2,400 copies per mL (equal to 480 copies/200 µL), which is about 500 copies/200 µL. (RMS 0034179.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 9.	
Claim 13. The method of claim 9, 10, 11 or 12 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 13.	

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
Claim 14. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma sample using HIV primers in about 30 cycles of PCR; and	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.

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(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 µl of plasma correlates positively with the conclusion that the anti-HIV agent is therapeutically effective.	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) The product labels state that the tests measure the copy number of HIV-1 RNA. (STAN 007454; STAN 007632; STAN 007575; STAN 031769.) This measurement is performed on the product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The labels for the AMPLICOR Tests further indicate that changes in HIV RNA copy number correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18.) For example, a 5-fold change in HIV RNA copy number is identified as providing statistically significant predictive value regarding the effectiveness of anti-HIV therapy. (STAN 007488-502.) A 5-fold decrease that results in a copy number less than about 200 per 200 µl (or 1000 per mL) of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically effective. Educational materials distributed by Roche indicate that drops in viral load to below 1000 copies/mL (i.e., 200 per 200 µl) correlate with a conclusion that therapy is effective. (RMS 0034261; RMS 0034268.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 14.	
Claim 18. The method of claim 14, 15, 16 or 17 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 18.	

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Claim 19. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(i) collecting one pre-treatment plasma sample from an HIV-infected patient who is about to be treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Test indicate that, when using the tests, a pre-treatment plasma sample is obtained from an HIV-infected patient. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The AMPLICOR Tests' product labels and the Roche web site expressly discuss the use of the AMPLICOR Tests to monitor the effectiveness of antiretroviral therapy in patients who are receiving therapy for the first time. (STAN 007488; STAN 007657; STAN 007615; STAN 029720; STAN 029868.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) collecting a post-treatment plasma sample from the HIV-infected patient after the patient has been treated with the antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The labels indicate that the AMPLICOR Tests are intended for use in monitoring the effectiveness of antiretroviral treatment wherein HIV RNA levels are measured over the course of treatment. (STAN 007629; STAN 007454; STAN 007569.) The AMPLICOR Tests' product labels and the Roche web site discuss the use of the AMPLICOR Tests to monitor the effectiveness of antiretroviral therapy through collection of plasma samples after antiretroviral treatment. (STAN 007488; STAN 0007657; STAN 007615; STAN 029720; STAN 029868.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

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(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;	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iv) measuring the HIV RNA copy number using the products of the PCRs of step (iii); and	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA in plasma. (STAN 007457; STAN 007632; STAN 007573; STAN 031769-74.) The product labels state that the tests measure the copy number of HIV-1 RNA. (STAN 007454; STAN 007632; STAN 007575; STAN 031769-74.) This measurement is performed on the product of the PCR amplification of step (iii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(v) comparing the HIV RNA copy number in pre-treatment and post-treatment plasma samples,	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 031769.) The labels for the AMPLICOR Tests and marketing materials distributed by Roche further indicate that changes in HIV RNA copy number correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18; RMS 0034238-80.) The method of measuring changes in HIV RNA copy number described by the AMPLICOR Tests' product labels involves comparing pre-and post-therapy copy numbers from plasma samples. (*Id.*) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '730 PATENT	INFRINGING PRODUCTS
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 FDA approved product labels for the AMPLICOR Tests identify 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; STAN 007657-63.) For example, a 5-fold change in HIV RNA copy number is identified as providing statistically significant predictive value regarding the effectiveness of anti-HIV therapy. (STAN 007488-502.) Roche's web site and other marketing materials distributed by Roche further indicate that changes in viral load of 3 to 1 or less are within the margin of error for standard tests of viral load; this teaches that declines in viral load of about 4 to 1 or greater indicate therapeutic efficacy. (STAN 029722-24; STAN 029870-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 19.	
Claim 23. The method of claim 19, 20, 21 or 22 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 23.	

U.S. PATENT 6,503,705

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
Claim 1. A method of evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient comprising:	The FDA approved product labels for the AMPLICOR HIV-1 MONITOR Test and the COBAS AMPLICOR HIV-1 MONITOR Test ("the AMPLICOR Tests") and the COBAS TaqMan HIV-1 Test ("the TaqMan Test") indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
a) collecting statistically significant data useful for determining whether or not a decline in plasma HIV RNA copy numbers exists after initiating treatment of an HIV-infected patient with an antiretroviral agent by:	The FDA approved product labels and marketing materials distributed by Roche for the AMPLICOR Tests identify 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; STAN 007657-63; RMS 0034238-80.) The sensitivity of the AMPLICOR Tests allow for the measurement of statistically significant changes, and Roche instructs patients and physicians to collect statistically significant data relating to changes in plasma HIV RNA copy numbers. (STAN 007486-87; STAN 029722-24; STAN 029870-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
(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;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, multiple plasma samples are obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007455-56; STAN 007584; STAN 007630-31; STAN 007639; STAN 031769; RMS 0008674; RMS 078692; RMS 078731.) The product labels and web sites for the AMPLICOR Tests further state that the tests are intended to be used to monitor the effects of antiretroviral therapy on HIV RNA copy number over a time interval (i.e., viral load before and after treatment). (STAN 007454-58; STAN 007629-33, STAN 007569-75; STAN 029720; STAN 029868.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The sensitivity of the AMPLICOR and TaqMan Tests allows for the measurement of statistically significant changes, and Roche instructs patients and physicians to look for statistically significant changes in viral load. (STAN 007486-87; STAN 029722-24; STAN 029870-72; RMS 0034238-

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
	80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iii) measuring HIV RNA copy numbers using the products of the PCR of step (ii);	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) The product labels state that the tests measure the copy number of HIV-1 RNA. (STAN 007454; STAN 007632; STAN 007575; STAN 031771.) This measurement is performed on the product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

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(iv) comparing the HIV RNA copy numbers in the plasma samples collected during the treatment; and	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 031769.) The labels for the AMPLICOR Tests and marketing materials distributed by Roche further indicate that changes in HIV RNA copy number correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18; RMS 0034238-80.) The method of measuring changes in HIV RNA copy number described by the AMPLICOR Tests' product labels involves comparing HIV RNA copy numbers from plasma samples collected during treatment. (*Id.*) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
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 FDA approved product labels for the AMPLICOR Tests identify 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; STAN 007657-63; RMS 0008674; RMS 078692; RMS 078731.) The sensitivity of the AMPLICOR Tests allow for the measurement of statistically significant changes, and Roche instructs patients and physicians to look for statistically significant changes in viral load. (STAN 007486-87; STAN 029722-24; STAN 029870-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 1.	
Claim 5. The method of claim 1 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 5.	

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
Claim 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 FDA approved product labels for the AMPLICOR Tests identify various changes in copy number that correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18.) The AMPLICOR Tests' product labels and Roche's AMPLICOR Test web site indicate that statistically significant declines in HIV RNA copy number correlate positively with the conclusion that an antiretroviral agent is therapeutically effective. (STAN 007488-502; STAN 029716-25; STAN 029801-07; STAN 029864-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 6.	
Claim 7. The method of claim 1, wherein the absence of a statistically significant decline in plasma HIV RNA copy numbers correlates positively that the antiretroviral agent is therapeutically ineffective.	The FDA approved product labels for the AMPLICOR Tests identify various changes in copy number that correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18.) The AMPLICOR Tests' product labels and Roche's AMPLICOR Test web site indicate that the absence of statistically significant declines in HIV RNA copy number correlate positively with the conclusion that an antiretroviral agent is therapeutically ineffective. (STAN 007488-502; STAN 029716-25; STAN 029801-07; STAN 029864-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 7.	
Claim 8. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
(i) collecting a pre-treatment plasma sample from the HIV-infected patient who is about to be treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a pre-treatment plasma sample is obtained from an HIV-infected patient who is about to be treated with an antiretroviral agent. (STAN 007455-56; STAN 007584; STAN 007630-31; STAN 007639; STAN 031769; RMS 0008674; RMS 078692; RMS 078731.) The AMPLICOR Tests' product labels and the Roche web site expressly discuss the use of the AMPLICOR Tests to monitor the effectiveness of antiretroviral therapy in patients who have not yet begun antiretroviral treatment. (STAN 007488; STAN 007657; STAN 007615; STAN 029720; STAN 029868.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(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 FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a post-treatment plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769.) The AMPLICOR Tests' labels indicate that they are intended for use in monitoring the effectiveness of antiretroviral treatment wherein HIV RNA levels are measured over the course of treatment. (STAN 007629; STAN 007454; STAN 007569; RMS 0008674; RMS 078692; RMS 078731.) The AMPLICOR Tests' product labels and marketing materials distributed by Roche discuss the use of the AMPLICOR Tests to monitor the effectiveness of antiretroviral therapy through collection of plasma samples after antiretroviral treatment. (STAN 007488; STAN 007657; STAN 007615; STAN 029720; STAN 029868; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
(iii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
(iv) measuring HIV RNA copy numbers using the products of the PCR of step (iii);	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) The product labels state that the tests measure the copy number of HIV-1 RNA. (STAN 007454; STAN 007632; STAN 007575; STAN 031771.) This measurement is performed on the product of the PCR amplification of step (iii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(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	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) The labels for the AMPLICOR Tests and marketing materials distributed by Roche further indicate that changes in HIV RNA copy number correlate to the effectiveness of anti-HIV therapy. (STAN 007488-502; STAN 007657-62; STAN 007615-18; RMS 0034238-80.) The method of measuring changes in HIV RNA copy number described by the AMPLICOR Tests' product labels involves comparing pre-and post-therapy copy numbers from plasma samples. (*Id.*) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
(vi) 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 FDA approved product labels for the AMPLICOR Tests identify 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; STAN 007657-63; RMS 0008674; RMS 078692; RMS 078731.) The sensitivity of the AMPLICOR Tests allow for the measurement of statistically significant changes, and Roche instructs patients and physicians to look for statistically significant changes in viral load. (STAN 007486-87; STAN 029722-24; STAN 029870-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 8.	
Claim 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 (sic).	The FDA approved product labels for the AMPLICOR Tests identify 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; STAN 007657-63.) For example, a 5-fold change in HIV RNA copy number is identified as providing statistically significant predictive value regarding the effectiveness of anti-HIV therapy. (STAN 007488-502.) Because Roche's web site further indicates that changes in viral load of 3 to 1 or less are within the margin of error for standard tests of viral load, a change in viral load of 7 to 1 or greater is indicative of therapeutic efficacy. (STAN 029722-24; STAN 029870-72.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 9.	

LIMITATIONS OF THE '705 PATENT	INFRINGING PRODUCTS
Claim 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 (sic).	The FDA approved product labels for the AMPLICOR Tests identify 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; STAN 007657-63.) For example, a 5-fold change in HIV RNA copy number is identified as providing statistically significant predictive value regarding the effectiveness of anti-HIV therapy. (STAN 007488-502.) Roche's web site and other marketing materials distributed by Roche further indicate that changes in viral load of 3 to 1 or less are within the margin of error for standard tests of viral load; this teaches that declines in viral load of about 4 to 1 or greater indicate therapeutic efficacy. (STAN 029722-24; STAN 029870-72; RMS 0034238-80.) The FDA approved product label and the Roche web site teach that the TaqMan Test is to be used as a substitute for the AMPLICOR Tests. (STAN 031794-98; STAN 031805-08.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 10.	

U.S. PATENT 7,129,041

LIMITATIONS OF THE '041 PATENT	INFRINGING PRODUCTS
Claim 1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:	The FDA approved product labels for the AMPLICOR HIV-1 MONITOR Test and the COBAS AMPLICOR HIV-1 MONITOR Test ("the AMPLICOR Tests") and the COBAS TaqMan HIV-1 Test ("the TaqMan Test") indicate that the AMPLICOR and TaqMan Tests are intended for use in monitoring the effects of antiretroviral therapy. (STAN 007629; STAN 007454; STAN 007569; STAN 031769; RMS 0034276; RMS 078691; RMS 078663; RMS 079168.) Roche sponsored studies of the AMPLICOR Tests with the specific goal of gaining FDA approval for their use to evaluate the effectiveness of anti-HIV therapy, and Roche distributes marketing materials that promote the use of the AMPLICOR Tests to monitor anti-HIV therapy. (RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '041 PATENT	INFRINGING PRODUCTS
correlating the presence or absence of detectable HIV-encoding nucleic acid in a plasma sample of an HIV infected patient with an absolute CD4 count, wherein the presence or absence of said detectable HIV-encoding nucleic acid is determined by	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence or absence of HIV-encoding nucleic acids in the plasma sample of an HIV-infected patient. (STAN 007457; STAN 007632; STAN 007573; STAN 031769; RMS 0008668; RMS 078691; RMS 078692; RMS 078663; RMS 078693; RMS 078826.) The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, HIV-encoding nucleic acid in a plasma sample from an HIV-infected patient is measured. (STAN 007630-31; STAN 007455-56; STAN 007584; STAN 007639; STAN 031769.) According to standard practice, CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The FDA approved product labels for the AMPLICOR Tests refer to CD4 count throughout, and the clinical studies cited in both labels correlated the presence of detectable HIV-encoding nucleic acid and CD4 counts with evaluations of the effectiveness of therapy. (STAN 007629; STAN 007658-62; STAN 007570; STAN 007617-21.) The TaqMan Test's product label also refers to CD4 count as an important indicator of patient status. (STAN 031769; STAN 031796-98.) In describing how the AMPLICOR Tests should be used, Roche's marketing materials and FDA submissions state that viral load results should be used in conjunction with CD4 counts to determine if antiretroviral therapy is effective, with effective treatment shown by the correlation of high CD4 counts with undetectable viral counts and ineffective treatment shown by low CD4 counts with detectable viral counts. (STAN 029704-21; STAN 029788-806; RMS 0014322; RMS 0014338-39; RMS 0022770; RMS 0023762; RMS 0034238-80.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
(i) collecting a plasma samples (sic) from an HIV-infected patient who is being treated with an antiretroviral agent;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that, when using the tests, a plasma sample is obtained from an HIV-infected patient who is being treated with an antiretroviral agent. (STAN 007630-31; STAN 007639; STAN 007455-56; STAN 007584; STAN 031769; STAN 031778; RMS 0008674; RMS 078692; RMS 078731.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
(ii) amplifying HIV-encoding nucleic acid that may be present in the plasma sample using HIV primers via PCR and;	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests involve the amplification of HIV-encoding nucleic acid that may be present using HIV primers via PCR. (STAN 007472; STAN 007640; STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; STAN 031771; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.

LIMITATIONS OF THE '041 PATENT	INFRINGING PRODUCTS
(iii) testing for the presence of HIV-encoding nucleic acid sequence in the product of the PCR.	The FDA approved product labels for the AMPLICOR and TaqMan Tests indicate that the tests obtain quantitative measurement of HIV-1 viral RNA, thereby revealing the presence of HIV-encoding nucleic acids in the plasma sample. (STAN 007457; STAN 007632; STAN 007573; STAN 031769.) This measurement is performed on the product of the PCR amplification of step (ii). (STAN 007456-57; STAN 007572-73; STAN 007631-32; STAN 031769-74; RMS 0008668; RMS 07869-93; RMS 078663-64; RMS 078826.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 1.	
Claim 2. The method of claim 1, wherein the absence of HIV-encoding nucleic acid and the absolute CD4 count being greater than about 200 cells per cubic millimeter correlate positively with the conclusion that the antiretroviral agent is therapeutically effective.	According to standard practice, CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The FDA approved product labels for the AMPLICOR Tests refer to CD4 count throughout, and the clinical studies cited in both labels correlated the presence of detectable HIV-encoding nucleic acid and CD4 counts with evaluations of the effectiveness of therapy. (STAN 007629; STAN 007658-62; STAN 007570; STAN 007617-21.) The TaqMan Test's product label also refers to CD4 count as an important indicator of patient status. (STAN 031769; STAN 031796-98.) In describing how the AMPLICOR Tests should be used, Roche's marketing materials and FDA submissions state that viral load results should be used in conjunction with CD4 counts to determine if antiretroviral therapy is effective, with effective treatment shown by the correlation of high CD4 counts with undetectable viral counts and ineffective treatment shown by low CD4 counts with detectable viral counts. (STAN 029704-21; STAN 029788-806; RMS 0014322; RMS 0014338-39; RMS 0022770; RMS 0023762; RMS 0034238-80.) Roche's web site instructs that a CD4 count of greater than 200 cells per cubic millimeter is significant in determining whether an antiretroviral agent is effective. (STAN 029704-21; STAN 029788-806.) Other educational materials distributed by Roche similarly refer to CD4 counts of 200 cells/mL or greater as significant. (RMS 0008621; RMS 0008623.) The TaqMan Test product label also identifies a CD4 count of greater than 200 cells per cubic millimeter as an important threshold (STAN 031796-98.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 2.	

LIMITATIONS OF THE '041 PATENT	INFRINGING PRODUCTS
Claim 3. The method of claim 1, wherein the presence of HIV-encoding nucleic acid and the absolute CD4 count being less than about 200 cells per cubic millimeter correlate positively with the conclusion that the antiretroviral agent is therapeutically ineffective.	According to standard practice, CD4 counts are routinely determined in connection with the quantitation of HIV RNA. The FDA approved product labels for the AMPLICOR Tests refer to CD4 count throughout, and the clinical studies cited in both labels correlated the presence of detectable HIV-encoding nucleic acid and CD4 counts with evaluations of the effectiveness of therapy. (STAN 007629; STAN 007658-62; STAN 007570; STAN 007617-21.) The TaqMan Test's product label also refers to CD4 count as an important indicator of patient status. (STAN 031769; STAN 031796-98.) In describing how the AMPLICOR Tests should be used, Roche's marketing materials and FDA submissions state that viral load results should be used in conjunction with CD4 counts to determine if antiretroviral therapy is effective, with effective treatment shown by the correlation of high CD4 counts with undetectable viral counts and ineffective treatment shown by low CD4 counts with detectable viral counts. (STAN 029704-21; STAN 029788-806; RMS 0014322; RMS 0014338-39; RMS 0022770; RMS 0023762; RMS 0034238-80.) Roche's web site instructs that a CD4 count of less than 200 cells per cubic millimeter is significant in determining whether an antiretroviral agent is effective. (STAN 029704-21; STAN 029788-806.) Other educational materials distributed by Roche similarly refer to CD4 counts of 200 cells/mL or less as significant. (RMS 0008621; RMS 0008623.) The TaqMan Test product label also identifies a CD4 count of less than 200 cells per cubic millimeter as an important threshold (STAN 031796-98.) The use of the AMPLICOR or TaqMan Tests infringe this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 3.	

LIMITATIONS OF THE '041 PATENT	INFRINGING PRODUCTS
Claim 4. The method of any one of claims 1–3, wherein the PCR is performed for about 30 cycles.	The FDA approved product label for the AMPLICOR HIV-1 MONITOR Test (in both its original form and version 1.5) specifies the use of about 30 cycles of PCR for amplification of HIV-encoding nucleic acid from the plasma sample using HIV primers. (STAN 007472; STAN 007640; RMS 078692; RMS 078663; RMS 0008667; RMS 078704; RMS 078670.) The FDA approved label and materials submitted by Roche to the FDA for the COBAS AMPLICOR HIV-1 MONITOR Test similarly indicate that the COBAS AMPLICOR Analyzer is pre-programmed to repeat PCR amplification for about 30 cycles of PCR upon user input that the COBAS AMPLICOR HIV-1 MONITOR Test is being used. (STAN 007572; RMS 0035567; RMS 0035630-31; RMS 0037980; RMS 0037913-15; RMS 079010; RMS 079031.) The use of the AMPLICOR Tests infringes this element literally or under the doctrine of equivalents. The FDA approved product label for the TaqMan Test indicates that the COBAS TaqMan Analyzer and COBAS TaqMan 96 Analyzer are preprogrammed to perform PCR amplification of HIV-encoding nucleic acid in the plasma sample. (STAN 031771.) The FDA approved product label further specifies that the analyzers perform 30 cycles or more of PCR amplification, with sample measurement occurring at about 30 cycles of PCR. (STAN 031772-73.) The use of the TaqMan Test infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 4.	
Claim 8. The method of any one of claims 1–3 in which the antiretroviral agent is zidovudine.	Zidovudine is AZT, one of the most commonly used antiretroviral agents. Zidovudine is one of the referenced antiretroviral agents in the AMPLICOR HIV-1 MONITOR Test, COBAS AMPLICOR HIV-1 MONITOR Test, and COBAS TaqMan HIV-1 Test product labels. (STAN 007488; STAN 007657; STAN 007602; STAN 007616; STAN 031788.) Marketing materials distributed by Roche also teach the use of the AMPLICOR Tests to monitor treatment with zidovudine. (RMS 0034240-74.) The use of the AMPLICOR or TaqMan Tests infringes this element literally or under the doctrine of equivalents.
Stanford asserts that manufacture, sale, offer of sale, and/or use of the AMPLICOR or TaqMan Tests directly infringes, contributorily infringes, and induces others to infringe claim 8.	