Appendix

Appendix
Asserted Claims and Disputed Terms

U.S. Patent No. 5,968,730

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.

5. The method of claim 1, 2, 3 or 4 in which the antiretroviral agent is zidovudine.

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;
   (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 presence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective.

7. 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 presence of detectable HIV-encoding nucleic acid correlates positively with an absolute CD4 count of less than 200 cells per cubic millimeter.

8. 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 sequence in the product of the PCR;
   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.

9. 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) 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.

13. The method of claim 9, 10, 11 or 12 in which the antiretroviral agent is zidovudine.

14. 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) 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.

18. The method of claim 14, 15, 16 or 17 in which the antiretroviral agent is zidovudine.

19. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising
(i) collecting one pre-treatment plasma sample from an HIV-infected patient who is about to be treated with an antiretroviral agent;
(ii) collecting a post-treatment plasma sample from the HIV-infected patient after the patient has been treated with the antiretroviral agent;
(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;
(iv) measuring the HIV RNA copy number using the products of the PCRs of step (iii); and
(v) comparing the HIV RNA copy number in pre-treatment and post-treatment plasma samples,
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.

23. The method of claim 19, 20, 21 or 22 in which the antiretroviral agent is zidovudine.

U.S. Patent No. 6,503,705

1. A method of evaluating the effectiveness of anti-HIV therapy of an HIV-infected patient comprising:

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:

(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;

(ii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;

(iii) measuring HIV RNA copy numbers using the products of the PCR of step (ii);

(iv) comparing the HIV RNA copy numbers in the plasma samples collected during the treatment; and

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.

5. The method of claim 1 in which the antiretroviral agent is zidovudine.

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.

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.

8. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:

(i) collecting a pre-treatment plasma sample from the HIV-infected patient who is about to be treated with an antiretroviral agent;

(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;

(iii) amplifying the HIV-encoding nucleic acid in the plasma samples using HIV primers via PCR for about 30 cycles;

(iv) measuring HIV RNA copy numbers using the products of the PCR of step (iii);

(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

(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.

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.

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.

U.S. Patent No. 7,129,041

1. A method of evaluating the effectiveness of anti-HIV therapy of a patient comprising:
   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
   (i) collecting a plasma samples from an HIV-infected patient who is being treated with an antiretroviral agent;
   (ii) amplifying HIV-encoding nucleic acid that may be present in the plasma sample using HIV primers via PCR and;
   (iii) testing for the presence of HIV-encoding nucleic acid sequence in the product of the PCR.

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.

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.

4. The method of any one of claims 1-3, wherein the PCR is performed for about 30 cycles.

8. The method of any one of claims 1-3 in which the antiretroviral agent is zidovudine.