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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

vs.

ROCHE MOLECULAR SYSTEMS, INC.; ROCHE DIAGNOSTICS CORPORATION; ROCHE DIAGNOSTICS OPERATIONS, INC.,

Defendants.

CASE NO. C-05-04158 MHP

DEFENDANTS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT OF OWNERSHIP OF AND LICENSE TO THE '730 AND '705 PATENTS; AND

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

[REDACTED VERSION]

Date: December 4, 2006
Time: 2:00 p.m.
Place: Hon. Marilyn H. Patel

4972/1985744.1

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TABLE OF AUTHORITIES

Page

Cases

Statutes

Other Authorities

Notice of Motion and Motion

PLEASE TAKE NOTICE that at 2:00 p.m. on December 4, 2006, or as soon thereafter as counsel may be heard, Defendants and Counterclaimants Roche Molecular Systems, Inc., Roche Diagnostics Corp., and Roche Diagnostics Operations, Inc. (collectively, "Roche"), will, and hereby do, move pursuant to Federal Rule of Civil Procedure 56 for summary judgment that Roche owns a pro rata undivided interest in, or, in the alternative, a non-exclusive, royalty-free license to, United States Patent Nos. 5,968,730 ("'730 Patent") and 6,503,705 ("'705 Patent").

MEMORANDUM OF POINTS AND AUTHORITIES

Preliminary Statement

As Drs. Mark Holodniy and Thomas Merigan acknowledge, in the late 1980s Cetus Corporation was the "engine behind the burgeoning use of PCR technology." And it's no wonder. After the groundbreaking and Nobel Prize-winning technology was invented at Cetus in the early 1980s, Cetus researchers realized that PCR[1] had tremendous clinical potential. As such, Cetus explored many potential uses for PCR, including the use of PCR to detect and quantitate HIV--the virus that causes AIDS. These efforts eventually resulted in many Cetus publications and patents.

Researchers from around the world approached Cetus in an effort to learn PCR techniques and information. One such group from Stanford University, headed by Dr. Thomas Merigan--the director of Stanford's Center for AIDS Research and a member of Cetus's Scientific Advisory Board since 1979--sought to obtain access to Cetus's technology for use in connection with Stanford's HIV research. In 1988, Cetus, Stanford, Merigan, and Dr. David Schwartz, a physician specialist who worked in Merigan's lab, entered into a Materials Transfer Agreement (the "MTA"). Pursuant to the MTA, Cetus provided Stanford access to its materials, and technical know-how related to PCR and HIV research. Stanford agreed that should its researchers invent anything of commercial value while using Cetus's materials or technical information, Cetus would have the right to a royalty-free non-exclusive license at its option. By its terms, the MTA covered

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[1] PCR or "polymerase chain reaction" is a molecular biology technique that permits scientists to generate billions of copies of a target DNA sequence in a matter of hours.

all materials and information given to Stanford researchers during the Cetus/Stanford PCR collaboration, whether used at Cetus or Stanford.

Thereafter, at Merigan's urging, Holodniy, a Stanford research fellow working in Merigan's laboratory, went to Cetus to learn PCR techniques related to the quantitation of the amount of HIV using PCR. In order to gain unfettered access to Cetus facilities and information, Holodniy was required to execute a Visitor's Confidentiality Agreement. That agreement provided for the assignment to Cetus of Holodniy's interest in any invention, idea, or improvement he conceived or made as a consequence of his access to Cetus's facilities or information. Holodniy entered Cetus a blank slate and left, after working at Cetus for nine months in 1989, with a five step assay for quantitating of HIV RNA using PCR. Later, Holodniy would claim that this assay entitled him to inventor status on the patents-in-suit issued to Stanford.

Now, despite the parties' joint efforts, Stanford seeks to enforce the '730 and '705 Patents in direct contravention of both the patent laws and the express terms of the parties' agreements. Because the undisputed evidence demonstrates that Defendants have an ownership interest in the subject matter of these patents, summary judgment on Roche's affirmative defenses related to ownership and license is warranted at this time.

Factual Background

A. Cetus's Discovery of PCR

Cetus is universally recognized as the discoverer of PCR--or Polymerase Chain Reaction. *See, e.g.*, Declaration of T.J. Chiang in Support of Roche's Motion for Summary Judgment ("Chiang Decl."), Ex. 46 (Holodniy Dep.) at 84:19-85:11. In the mid-1980s, Kary Mullis, a Cetus scientist, conceived of a method for making multiple copies of DNA in the laboratory. *See generally E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 WL 305551 at *1 (N.D. Cal. 1990). The development of PCR by Cetus researchers allowed scientists for the first time to make billions of copies of specific sequences of DNA from only a few starting molecules. *See id.* For its efforts, Cetus obtained numerous patents covering PCR technology, and Kary Mullis was awarded the Nobel Prize for chemistry. Chiang Decl., Ex. 46 (Holodniy Dep.) at 85:12-21.

B. Cetus's Work with PCR and HIV

Shortly after conceiving of PCR, Cetus turned its attention to potential applications for the technique. Beginning in 1985, Cetus began a project aimed at developing methods and techniques for detecting and quantifying HIV in patient blood using PCR. *See* Declaration of John J. Sninsky, Ph.D. in Support of Roche's Motion for Summary Judgment ("Sninsky Decl."), ¶¶ 5-9; *see also* Chiang Decl., Ex. 51 (Kwok Dep.) at 46:8-15. This work drew the attention of Stanford researchers including Drs. Thomas Merigan and Mark Holodniy. Chiang Decl., Ex. 46 (Holodniy Dep.) at 74:17-75:13.

C. The Collaboration Between Cetus and Stanford

1. Stanford Seeks Cetus Protocols for Quantitation of HIV Using PCR

Merigan, a Stanford professor and Director of Stanford's Center for AIDS Research, was a long-time Cetus consultant and member of Cetus's Scientific Advisory Board. Chiang Decl., Exs. 1-3 (Merigan agreements), Ex. 48 (Merigan Dep.) at 24:3-25:14, 73:10-14, 92:3-7, 95:19-99:1. Throughout the 1980s, Merigan entered into a number of Materials Transfer Agreements with Cetus pursuant to which Cetus provided Merigan and his colleagues with Cetus's proprietary materials and information. Chiang Decl., Exs. 4-6 (Merigan/Cetus MTAs); Ex. 48 (Merigan Dep.) at 223:12-224:15, 230:16-231:5. In return, the parties understood that should anything useful be developed by Stanford using Cetus materials or information, Cetus was entitled, at a minimum, to a non-exclusive, royalty-free license to any intellectual property developed as a result of the MTA. Chiang Decl., Ex. 50 (Ostrach Dep.) at 91:5-94:25; *see also* Chiang Decl., Ex. 5, ¶ 8; Ex. 6, ¶ 8; Ex. 57, ¶ 8.

In 1988, Cetus and Stanford were involved in a clinical trial exploring the efficacy of using the drug IL-2 in connection with the treatment of AIDS patients. *See* Declaration of Dr. Eric S. Groves in Support of Roche's Motion for Summary Judgment ("Groves Decl."), ¶ 4; Chiang Decl., Ex. 47 (Schwartz Dep.) at 48:20-50:20. Drs. Merigan and David Schwartz, a Stanford physician specialist, headed the Stanford team. Chiang Decl., Ex. 46 (Holodniy Dep.) at 18:16-23; Ex. 47 (Schwartz Dep.) at 48:20-49:8; Ex. 8 (Merigan letter). Eric Groves, the director of Cetus's Clinical Biology group, spearheaded the effort at Cetus. Groves Decl., ¶ 4. As part of that trial,

Stanford provided access to samples from AIDS patients, while Cetus provided the IL-2 drug to be given to patients. *Id.* Cetus also used PCR to quantitate the HIV levels of patients in the trial. *Id.*, ¶ 5; Chiang Decl., Ex. 47 (Schwartz Dep.) at 49:24-50:13.

Throughout the summer and fall of 1988, Cetus shared the results of its PCR testing with Merigan and Schwartz. Groves Decl., ¶¶ 6-8; Ex. 1; Chiang Decl., Ex. 52 (Groves Dep.) at 45:6-46:23. Subsequently, Stanford sought to independently reproduce the PCR results that were being generated by Cetus. Chiang Decl., Ex. 8 (Merigan letter). In a November 7, 1988 letter, Merigan and Schwartz, both of whom had extremely limited PCR experience,[2] sought to obtain "a written copy of the Cetus protocol for extraction, amplification and quantitation of HIV DNA" using PCR. Chiang Decl., Ex. 8 at CH743 (Merigan letter). According to the letter, Stanford sought to "duplicate the conditions of pcr as run at Cetus." *Id.* The letter also made clear that Stanford wanted detailed information regarding this protocol:

> I would really appreciate the kind of detailed protocol that would enable a technician to start with frozen cell samples, extract the DNA, set up the exact PCR conditions and liquid hybridization and quantitation from scratch. Only in this way can we do a step-by-step comparison of our results.

Id.

2. The December 1988 Materials Transfer Agreement

As a consequence of Merigan and Schwartz's request, Cetus, on the one hand, and Merigan and Schwartz, and Stanford, on the other, by letter dated December 19, 1988,[3] entered into a Materials Transfer Agreement (the "MTA") pursuant to which Cetus provided Stanford with "certain research substances and know-how for the purpose of scientific collaboration. . . . " *See* Chiang Decl., Ex. 10; Groves Decl., ¶ 10. This MTA, which was substantially similar to previous MTAs in place between Stanford and Cetus, was intended to protect Cetus's intellectual property

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[2] By his own admission, Merigan had no PCR laboratory experience as of 1988, and Schwartz had no PCR experience before his interaction with Cetus, Chiang Decl., Ex. 45 (Merigan Interrogatory Response No. 1) ("Dr. Merigan has never performed PCR himself. . . . "); Ex. 48 (Merigan Dep.) at 83:11-84:3, 90:24-91:1; Ex. 47 (Schwartz Dep.) at 13:5-15:2.

[3] Merigan, Schwartz, and Stanford executed the MTA in February 1989. Chiang Decl., Ex. 10.

rights and was understood by the parties to cover materials and information exchanged between them from the inception of the HIV project through to any success. *See* Groves Decl., ¶ 10; Chiang Decl., Ex. 50 (Ostrach Dep.) at 90:16-91:3; Ex. 47 (Schwartz Dep.) at 44:24-46:3, 60:19-61:9.

Under the MTA, Cetus agreed to provide Stanford with broad categories of "Materials" relating to HIV research using PCR including physical products, biological materials, and technical know-how relating to HIV and PCR including, without limitation:

> (a) appropriate oligonucleotide primers and probes for the detection of human immunodeficiency virus (HIV), HLA loci and both coded and noncoded control dilutions of HIV in uninfected DNA's to be used as controls for use with CETUS's proprietary polymerase chain reaction (PCR), and associated PCR technology; (b) any related biological material or associated know-how and data that will be received by [Drs. Merigan, Schwartz and their collaborators] from Cetus. . . . The MATERIAL is considered proprietary to CETUS.

Chiang Decl., Ex. 10, ¶ 2.

The MTA provides that the Stanford scientists "will inform CETUS, in confidence, of research results *related to the Material* . . . [and] *CETUS shall be free to use such data and information for any purpose*." *Id.*, ¶ 7 (emphasis added).[4] The MTA also provides that if Stanford's research involving the "Material" results in an invention or substance that may be commercially useful, Stanford will: (1) disclose the invention to Stanford's patent administrator and notify the same of Cetus's role as the supplier of the Material used and the role of Cetus employees in creating the invention; and (2) supply Cetus with a copy of such disclosure for Cetus's evaluation purposes. *Id.*, ¶ 8. Most importantly, like other MTAs between Stanford and Cetus, this MTA provided that in consideration of Cetus's provision of the "Materials" to Stanford, Cetus was entitled to an exclusive license to any resulting invention, at a reasonable royalty, or a royalty free, non-exclusive license, at Cetus's option:

> In consideration of CETUS' providing of the Material, INSTITUTION, to the extent it is legally able to do so, hereby grants CETUS the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith . . . , *or at*

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[4] The MTA further provides that should Stanford wish to publish the results of any research related to the "Material" provided by Cetus, Stanford agreed that it would seek approval from Cetus and give Cetus appropriate acknowledgment in such publications. *Id.*, ¶ 7.

CETUS' option, a nonexclusive license.

See id., ¶ 8 (emphasis added); *see also* Chiang Decl., Ex. 50 (Ostrach Dep.) at 91:21-94:16.

As set forth more fully below, Holodniy and researchers at Stanford received and used, both in the labs at Stanford and in the labs at Cetus, materials and information from Cetus covered by this agreement. Chiang Decl., Ex. 47 (Schwartz Dep.) at 31:3-32:3 (Holodniy used reagents from Cetus at Stanford in PCR reactions), 77:9-78:10 (same), 39:10-40:6 (primers at Stanford were brought back from Cetus by Holodniy), 46:23-47:5 (same), 76:2-18 (same), 39:10-41:12 (Stanford researchers used materials from Cetus in connection with the quantitation work), 55:9-56:9 (MTA covers materials used at Cetus and brought back to Stanford), 106:17-107:2 (materials covered by MTA ended up in Stanford's lab), 35:6-39:2 (detailing areas of collaboration regarding know-how with Cetus), 54:24-55:3 (received protocols), 56:10-57:7 (information gathered by Holodniy at Cetus covered by MTA); *see also id.* at 57:8-59:21.

3. Holodniy's Collaboration with Cetus

Holodniy joined Stanford in July 1988 as a fellow in the Division of Infectious Diseases. Chiang Decl., Ex. 46 (Holodniy Dep.) at 103:5-7. As Merigan informed him, Holodniy's fellowship program involved "working on HIV trials with antiretroviral drugs" and working to "develop some sort of marker to be able to assess the effectiveness of therapy." *Id.* at 103:24-104:18. Prior to joining Stanford in July 1988, however, Holodniy had no experience with conducting PCR and little or no experience with molecular biology laboratory techniques. Chiang Decl., Ex. 46 (Holodniy Dep.) at 83:9-85:4; Ex. 47 (Schwartz Dep.) at 32:4-33:1.

Holodniy began working in Merigan's lab in October 1988, just before Merigan and Schwartz requested Cetus's HIV protocols.[5] Chiang Decl., Ex. 46 (Holodniy Dep.) at 19:12-24. At that time, Merigan informed Holodniy that he would be working to "find a molecular based test to measure the effectiveness of antiviral treatments." Chiang Decl., Ex. 46 (Holodniy Dep.) at 113:12-114:1; Ex. 48 (Merigan Dep.) at 78:3-79:1, 80:10-81:11.

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[5] According to Merigan, his October request for Cetus protocols was intended to aid Holodniy's PCR effort. Chiang Decl., Ex. 48 (Merigan Dep.) at 281:13-21.

At the outset of his work, Schwartz provided Holodniy with some preliminary background concerning PCR.[6] Holodniy spent the next three months reviewing publications concerning fundamental aspects of PCR--not surprisingly, many were authored by Cetus researchers. Chiang Decl., Ex. 9 (Holodniy Art.) at 4; Ex. 46 (Holodniy Dep.) at 139:16-140:10; 143:2-144:16. During that time, Holodniy also engaged in some preliminary experiments, which by his own admission were only of limited success. *See* Chiang Decl., Ex. 46 (Holodniy Dep.) at 146:13-23. Recognizing the challenges faced by Holodniy, in early 1989 Merigan suggested that Holodniy "should spend some time at the Cetus Corporation in Emeryville, California, which at the time was the engine behind the burgeoning use of PCR technology." Chiang Decl., Ex. 9 (Holodniy Article) at 5; *see* Ex. 46 (Holodniy Dep.) at 147:19-148:13. Through his close relationship with Cetus, Merigan arranged for Holodniy to work at Cetus in an effort to learn PCR techniques related to using PCR to monitor the effectiveness of antiviral therapy in treating HIV patients. Chiang Decl., Ex. 46 (Holodniy Dep.) at 146:13-149:1; 152:20-154:13; Ex. 47 (Schwartz Dep.) at 26:11-28:11; Ex. 48 (Merigan Dep.) at 71:18-22. Up to that time, Holodniy admits that he had not yet engaged in any efforts to develop a quantitative PCR assay. Chiang Decl., Ex. 46 (Holodniy Dep.) at 146:13-147:3. According to Holodniy, "[t]hrough [Merigan's] ongoing collaboration and contact with Cetus scientists, I was fortunate to be able to spend the next year at Cetus working with some great molecular biologists and scientists." Chiang Decl., Ex. 9 (Holodniy Art.) at 5.

Holodniy began commuting daily to Cetus beginning in February 1989--within days of the execution of the MTA. Chiang Decl., Ex. 9 (Holodniy Art.) at 6; Ex. 10; Ex. 46 (Holodniy Dep.) at 13:24-14:5. As he admitted at deposition, Holodniy's purpose in going to Cetus was to obtain information from Cetus scientists regarding the feasibility and construction of a quantitative PCR assay for measuring HIV for purposes of monitoring treatment. Chiang Decl., Ex. 46 (Holodniy

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[6] Schwartz was initially tasked with heading the collaboration with Cetus concerning the quantitation of HIV in blood for the purposes of monitoring the efficacy of therapy. Chiang Decl., Ex. 47 (Schwartz Dep.) at 29:24-30:24; 53:9-15; 78:15-80:23. Schwartz felt the project was a "huge undertaking" given his limited molecular biology experience. *Id.* at 81:6-22. He was assured by Merigan, however, that "Cetus had tremendous expertise" and that any "problems could be overcome because there was a lot of experience at Cetus." *Id.*

Dep.) at 152:20-153:22. There, he was assigned a lab bench in Cetus's Clinical Group, and he had unfettered access to Cetus researchers, reagents, equipment, and technical expertise. *Id.* at Ex. 46 (Holodniy Dep.) at 31:17-25, 169:12-17; 182:21-184:1, 250:3-15; Groves Decl., ¶¶ 10-11.

Because of his broad access, Holodniy was obligated to execute a Cetus Visitor Confidentiality Agreement (the "Visitor Agreement") "to establish [his] presence there." Chiang Decl., Ex. 52 (Groves Dep.) at 99:5-102:7; Ex. 46 (Holodniy Dep.) at 155:8-18; Groves Dec., ¶ 11. The Visitor Agreement was in a form substantially similar to that executed by other Stanford visitors to Cetus including Merigan and Schwartz. Chiang Dec., Exs. 12 & 13. Pursuant to the Visitor Agreement, Holodniy agreed that:

Chiang Decl., Ex. 11. Holodniy executed the Visitor Agreement on February 14, 1989. *Id.*

Holodniy brought his Stanford-issued laboratory notebook with him to Cetus and numerous entries in his notebooks reflect his interactions with Cetus researchers and his use of Cetus's laboratory equipment, materials, and information.[7] Indeed, he spent so much time on the first floor of Cetus's main building that his own colleagues had a Cetus telephone number for him, and some Cetus employees initially thought that he was a member of the Cetus Clinical Group.

Chiang Decl., Ex. 46 (Holodniy Dep.) at 57:9-58:4; Ex. 14 (Sengupta Notebook) at STAN 16413 (*see* Holodniy admission, Ex. 46 at 388:23-389:8); Ex. 15 (Casipit Notebook) at CH 393. The Stanford lab notebooks of Holodniy's assistant, Sohini Sengupta, also reflects information, protocols, and materials that Holodniy took from Cetus and brought to Stanford.[8]

While at Cetus, Holodniy worked closely with a number of Cetus scientists during the effort to develop an assay that could be used to quantitate HIV RNA in blood samples for purposes of monitoring therapy. Chiang Decl., Ex. 46 (Holodniy Dep.) at 218:1-219:13. As Holodniy testified, his repeated requests for access to Cetus personnel, equipment, materials, and technical know-how were never denied. *Id.* at 183:8-184:1. During his nine months at Cetus, Holodniy received proprietary Cetus technical information from no fewer than twelve Cetus scientists[9] as well as voluminous physical materials with which he was able to conduct experiments.[10]

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[9] Holodniy testified that he interacted with at least the following Cetus personnel: Eric Groves, Michael Konrad, Alice Wang, Ernie Kawasaki, John Sninsky, David Gelfand, Clayton Casipit, Susanne Dewitt, Sharon Degroat, Paul Gumerlock, Sue Kim, and Shirley Kwok. Chiang Decl, Ex. 46 (Holodniy Dep.) at 218:1-219:13.

[10] It is undisputed that Holodniy and his colleagues at Stanford received at least the following physical materials from Cetus during the term of their collaboration: CC2; HRP-labeled SK19 probe; nucleic acid extraction reagents and associated buffers; primers for reverse transcription; reverse transcriptase enzyme; DNA polymerase; primers and reagents for PCR; gel and reagents for gel electrophoresis; avidin-coated beads; biotin labeled PCR primers; SK38 and SK39; and other oligonucleotides. Chiang Decl., Ex. 46 (Holodniy Dep.) at 72:7-19, 172:7-19, 174:21-175:5, 187:21-188:5, 190:19-21, 191:20-25, 215:23-216:6, 256:11-258:5, 258:10-259:5, 329:14-22. Holodniy also admits he received information from Cetus. *Id.* at 158:4-19 (quantitating the input and output of DNA), 166:21-167:25 (feasibility of quantitation), 170:20-171:6 (RNA extraction), 172:20-24 (reverse transcription), 177:3-22 (protocol for extraction and reverse transcription of RNA from serum), 180:14-25 (reverse transcription and extraction), 182:4-9 (amplification), 185:5-14 (isotopic detection of PCR products), 192:24-194:20 (advice and suggestions regarding quantitation standard), 198:10-200:25 (strategy for construction of standard), 202:4-20 (identifying primers to order), 203:22-204:14 (constructing a mutant gag gene sequence), 211:24-212:10 (colorimetric detection), 246:21-247:10 (techniques related to cellular DNA and RNA and (footnote continued)

Ultimately, an assay for quantitating HIV RNA using PCR was developed at Cetus (the "HIV RNA Quantitation Assay") that was comprised of five key steps. Chiang Decl., Ex. 46 (Holodniy Dep.) at 63:3-71:2; Ex. 22 (JID Art.). The first step--"extraction"--is to extract HIV RNA[11] from serum or plasma.[12] Chiang Decl., Ex. 46 (Holodniy Dep.) at 63:3-14; Ex. 22 (JID Art.). In the second step--"reverse transcription"--the single-stranded HIV RNA is copied into a double-stranded DNA molecule. Chiang Decl., Ex. 46 (Holodniy Dep.) at 63:15-22; Ex. 22, (JID Art.). In the third step--"amplification"--millions of copies of the HIV DNA are made by PCR using primers developed by Cetus such as SK38, SK39, and SK145.[13] Chiang Decl., Ex. 46 (Holodniy Dep.) at 63:15-22; Ex. 22, (JID Art.). In the fourth step--"detection"--the amplified DNA may then be detected using a short piece of complimentary DNA called a "probe." Chiang Decl., Ex. 46 (Holodniy Dep.) at 63:15-66:22; Ex. 22, (JID Art.). Cetus and Holodniy worked with a colorimetric detection system that used a horseradish peroxidase or "HRP" labeled probe. *Id.* This probe initiates a color change in a chemical reaction to show when targeted, amplified DNA is present in the sample. *Id.* In the final step--"quantitation"-- a cRNA standard is used to generate a standard curve so that the amount of virus in a patient's blood sample could be calculated. *Id.* at 66:23-67:15, 67:24-68:23; Ex. 22, (JID Art.).

The cRNA standard was crucial to the functionality of the HIV RNA Quantitation Assay. Chiang Decl., Ex. 46 (Holodniy Dep.) at 67:24-68:23, 70:10-72:24. Because Holodniy had no experience creating or using such standards or PCR for quantitation, Holodniy sought information

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serum RNA quantitation), 254:5-255:7 (extraction procedures for extraction of RNA), 286:1-10 (avidin-biotin protocol).

[11] HIV is a retrovirus. The genetic information for HIV is contained in a molecule called RNA. Chiang Decl., Ex. 56 (Kawasaki Dep.) at 31:9-32:19.

[12] Blood plasma is the fluid portion of blood remaining after cells have been removed. Websters Third New International Dictionary 237 (3d ed. 1961). Serum is blood plasma where the clotting agents have been removed. *Id.*

[13] The "SK" designation in the name of these primers and probes refers to Cetus employee Shirley Kwok who developed key primers for use with PCR and HIV. Chiang Decl., Ex. 46 (Holodniy Dep.) at 257:7-25.

from Cetus's Alice Wang who had substantial experience using PCR for quantitation of nucleic acids.[14] Chiang Decl., Ex. 46 (Holodniy Dep.) at 72:25-74:6. As Holodniy testified:

> Q. But she had experience, expertise using PCR for quantitation; is that correct?
> A. Yes.
> Q. And that's why you sought out information from her, correct?
> A. Yes.
> . . .
> Q. And at that time you approached her, you weren't an expert in that field, correct?
> A. I had not done any previous work in that field.
> Q. And you weren't an expert in that field, correct?
> A. Again, I --
> Q. You couldn't be an expert if you hadn't done work in the field, right?
> A. I hadn't done work in the field.
> Q. And you hadn't published in the field?
> A. I had not published in the field.
> Q. And you were at Cetus to learn information about that field, correct?
> A. That's correct.

Id. at 161:10-162:20; *see also id.* at 399:13-24.

In her initial meeting with Holodniy, Wang informed him that it would be feasible to develop an assay for quantitating HIV RNA by building a standard using techniques that she had previously employed. *Id.* at 166:21-167:25. Wang outlined how such a standard could be constructed. *Id.* at 167:9-25, 192:1-193:18, 198:2-200:25, 202:21-204:14, 208:23-209:7; 399:13-24. Because Holodniy had no experience constructing such a standard, however, Clayton Casipit, who worked in Wang's lab, spent many months constructing, testing, and validating that standard. Chiang Decl., Ex. 15 (Casipit Notebook) at CH 391-582; Ex. 54 (Casipit Dep.) at 17:8-18:24. This cRNA standard--also known as CC2 for "Clayton Casipit" 2--was provided to Holodniy in October 1989. *See* Chiang Decl., Ex. 46 (Holodniy Dep.) at 72:7-19, 261:11-25; Ex. 15 (Casipit Notebook) at CH 524; *see also* Ex. 43 (Holodniy Notebook) at STAN 3515.[15]

In discovery, Holodniy admitted that before working at Cetus he had no experience with

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[14] Wang was ultimately awarded a patent covering the technique that she developed for quantitating RNA using an internal standard. That patent, U.S. Patent No. 5,219,727, issued June 15, 1993 and is entitled "Quantitation of nucleic acids by the polymerase chain reaction." *See* Declaration of Rhea Nersesian in Support of Motion for Summary Judgment ("Nersesian Decl."), Ex. 6.

[15] This was the only cRNA standard used in connection with the HIV RNA Quantitation Assay prior to the filing of Stanford's original patent application on May 14, 1992. Chiang Decl., Ex. 46 (Holodniy Dep.) at 303:15-305:8, 310:10-13, 345:24-347:10; *see also* Ex. 20 (UCLA Abstract); Ex. 22 (JID Art.); Ex. 25 (JCI Art.).

any of the steps in the completed HIV RNA Quantitation Assay. For example, he admitted: (1) that he had never performed HIV RNA extraction; (2) that he had never performed reverse transcription of HIV RNA; (3) that he had never amplified reverse transcribed HIV DNA using PCR; (4) that he had never detected a PCR product using a colorimetric assay with an HRP-labeled probe; and (5) that he had never quantitated HIV RNA using PCR. Chiang Decl., Ex. 46 (Holodniy Dep.) at 155:23-157:24, 173:3-24, 254:2-262:3. Holodniy admits that he learned each of these steps while at Cetus, from Cetus researchers, using Cetus equipment, materials, and information. *Id.*

As Holodniy candidly testified, while being examined concerning a 1990 abstract presented at a UCLA symposium describing the development of the HIV RNA Quantitation Assay, it was Cetus's expertise, materials, and equipment that made the development of each step of the assay possible:

Q: Prior to going to Cetus you had never extracted HIV-1 RNA from [serum], correct?
A: That's correct.
Q: And you learned information from Cetus to enable you to do that, correct?
A: I had sought advice from people such as Dr. Kawasaki on the extraction procedures for extracting RNA.
Q: And he provided you with that information, right?
A: He provided me with the specific elements that would be required for a procedure to extract RNA.

. . .

Q: Prior to going to Cetus you had never reverse transcribed HIV RNA, right?
A: That's correct.
Q: And people at Cetus provided you with information on how to do that, right?
A: That's correct.
Q: And they provided you with materials so that you could accomplish that, correct?
A: They provided me with reagents to perform reverse transcriptase -- reverse transcription.
Q: And they provided you with equipment so that you could accomplish that as well, correct?
A: That's correct.

. . .

Q: Prior to going to Cetus, had you amplified HIV RNA?
A: No.
Q: The individuals that you interacted with at Cetus provided you with information on how to do that, didn't they?
A: To do --
Q: Amplification of HIV RNA?
A: They provided me with advice on how to set up a reverse transcription polymerase chain reaction assay for this particular gene.

. . .

Q: The materials necessary to conduct this amplification [were] provided to you by Cetus, is that correct?

A: Yes.
Q: And the equipment necessary to do that also provided by Cetus, right?
A: That's correct.
. . .
Q: And prior to working at Cetus, you had never worked -- you had never utilized an HRP probe, correct?
A: That's correct.
Q: And while you worked at Cetus, individuals there provided you with information concerning how to use such a probe, correct?
A: They gave me advice and suggestions on a procedure to be able to use that to develop the color reaction.
Q: And they also provided you with the HRP probe itself, correct?
A: That's correct.
Q: And they provided you with the equipment with which to use the probe, correct?
A: That's correct.
. . .
Q: In the last paragraph [of the abstract], there's reference to "An RNA gag gene sequence being used to quantitate viral copy number." Do you see that second sentence?
A: Yes.
Q: That's the cRNA standard that Clayton provided to you in the fall of 1989?
A: That was the RNA standard that we used in this assay, yes.
Q: And he handed you a tube that contained that material, correct?
A: That's correct.
Q: And prior to working with Cetus, you had never worked with a standard such as this, correct?
A: That's correct.

Chiang Decl., Ex. 46 (Holodniy Dep.) at 254:2-262:3; *see also id.* at 155:23-157:24, 173:3-24; Ex. 20 (UCLA Abstract).

4. First Publication of the Results of the Joint Work

Using the knowledge and experience he gained working at Cetus, in late 1989 Holodniy sought to publish the results of the work related to the development of the HIV RNA Quantitation Assay. Chiang Decl., Ex. 17 (Publication Clearance Request). In December 1989, as required by the MTA, Holodniy requested permission from Cetus to publish an abstract at the UCLA symposium (the "UCLA Abstract"). *Id.* Although he initially excluded Cetus contributors Alice Wang, Clayton Casipit, and Dr. Michael Konrad from the abstract, after correcting this omission at the request of Cetus's Eric Groves, permission to publish was granted. Chiang Decl., Ex. 18 (Letter to Merigan and Holodniy); Ex. 17. Cetus, however, requested that the information in the UCLA Abstract be kept confidential until publication due to a pending Cetus patent application; not surprisingly, Holodniy acknowledged at deposition that information in the abstract was

proprietary to Cetus. Chiang Decl., Ex. 46 (Holodniy Dep.) at 266:17-268:11, 270:6-273:7; Exs. 18 (Letter to Merigan and Holodniy); Ex. 19 (Letter to UCLA). The UCLA Abstract, entitled "Quantitation of HIV-1 RNA in Serum and Correlation with Disease Status Using the Polymerase Chain Reaction," concludes that the authors have demonstrated that HIV viral RNA can be detected and quantitated in patient serum and that such quantitation "may be a useful marker for disease progression or monitoring antiviral therapy." Chiang Decl., Ex. 20 (UCLA Abstract).

5. Dr. Holodniy Submits a Cetus Invention Disclosure

Shortly after obtaining permission to publish the UCLA Abstract, Holodniy also submitted to Cetus an invention disclosure covering the same work. Chiang Decl., Ex. 46 (Holodniy Dep.) at 275:1-278:4; Ex. 21 (Invention Disclosure). The invention disclosure, entitled "Quantitation of HIV-1 viral RNA in human serum utilizing an in vitro generated internal standard for coamplification and an enzyme linked affinity assay for detection" was submitted on January 9, 1990 for Holodniy by Konrad, a Cetus scientist in Groves's laboratory. Chiang Decl., Ex. 21 (Invention Disclosure). The invention disclosure not only described the parties' joint work in Holodniy's own handwriting, but also attached a copy of the UCLA Abstract and indicated that information related to the invention could be found in Holodniy's "Personal Lab book." Chiang Decl., Ex. 21 (Invention Disclosure); Ex. 46 (Holodniy Dep.) at 275:1-278:1; 281:19-282:4. It further indicated that the cRNA standard designed and constructed by Cetus researchers (Alice Wang and Clayton Casipit) had been used in the course of the invention. Chiang Decl., Ex. 21 (Invention Disclosure). Holodniy admits that Cetus considered the HIV RNA Quantitation Assay —the subject of the Invention Disclosure—to be proprietary and that he was obligated to submit that Invention Disclosure to Cetus under the terms of his Visitor Agreement:

Q: And this is a Cetus invention disclosure, right?
A: That's correct.
Q: Who provided you with the form?
A: I can't recall if this was actually Dr. Konrad or Dr. Groves.
Q: They provided you with this form because Cetus had an ownership interest with respect to the subject matter of this invention disclosure, right?
A: I believe that's what Dr. Groves was concerned about and interest about when they had instructed me to fill this form out.
Q: And you didn't reject their request to fill this form out, did you?
A: I did not.

Chiang Decl., Ex. 46 (Holodniy Dep) at 277:10-278:1, 278:13-21 ("there was wording in the visitor disclosure that basically stated that if there was something that was invented, it needed to be disclosed if -- during my time at Cetus"); *see also* Groves Decl., ¶ 11.

6. Continued Cetus/Stanford Joint Publication

In addition to providing the details for the invention disclosure, the UCLA Abstract subsequently formed the basis of an article published in the Journal of Infectious Diseases in April 1991 entitled "Detection and Quantification of Human Immunodeficiency Virus RNA in Patient Serum by Use of the Polymerase Chain Reaction" (the "JID Article"). Chiang Decl., Ex. 46 (Holodiny Dep.) at 303:15-305:8, 310:10-13; Ex. 22, (JID Art.). Listed authors include Holodniy, Sengupta, Drs. David Katzenstein and Merigan from Stanford, and Wang, Casipit, Konrad, and Groves from Cetus. Chiang Decl., Ex. 22, (JID Art.). This article has been identified as one of the most important articles in the Journal of Infectious Diseases in the last 100 years. Chiang Decl., Ex. 23 (Kuritzkes Art.).

The JID Article begins by noting that the authors demonstrated that HIV RNA was detected and quantified in the serum of HIV-positive individuals and that such quantification "may be useful as a marker for disease progression or in monitoring antiviral therapy." Chiang Decl., Ex. 22, (JID Article) at RMS 1468 (preamble). The article then describes the work that Cetus did that made HIV RNA quantification possible. In particular, it describes: (1) extraction of HIV RNA from a patient sample; (2) reverse transcription of the HIV RNA; (3) amplification of target DNA using Cetus information and materials taught to Holodniy; (4) detection of the targeted DNA using the HRP probe; and (5) quantitation of the virus in the sample using the cRNA standard designed and constructed at Cetus. *Id.* at RMS 1468-1469; *see also, supra*, at 11.

The JID Article summarizes that "[t]hese results demonstrate that HIV RNA in serum can be detected and quantitated by reverse transcription, PCR, and a nonisotopic enzyme-linked affinity assay." *Id.* at RMS 1470-1471. The article then refers to unpublished work by the authors that suggests that HIV RNA may be recovered and used even more easily from plasma. *Id.* at RMS 1471. Finally, the JID Article concludes that "[s]erum PCR may provide an additional

marker of disease progression and drug efficacy that could improve our ability to monitor the course of HIV infection." *Id.*[16]

D. Stanford Patents its Joint Work with Cetus

On May 14, 1992, Stanford's counsel submitted the parent application for the '730 Patent family. U.S. Patent No. 5,968,730, which ultimately issued on October 19, 1999, is entitled "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome." Chiang Decl., Ex. 27. The claims of the patent relate to, among other things, methods for: (1) amplifying HIV in serum or plasma[17] samples using HIV primers via PCR; and (2) measuring or quantitating HIV RNA copy numbers using the amplified PCR product. The named inventors are Merigan, Holodniy and Katzenstein.

The initial application identified only Merigan and Dr. Michael Kozal as inventors. Subsequently, in November 1992, the applicants petitioned to correct inventorship and sought to add Holodniy and Katzenstein as joint inventors. Chiang Decl., Ex. 31. In support of the petition, Barry Elledge, Stanford's prosecution counsel, represented to the PTO under penalty of perjury that Holodniy made the following alleged contributions to the subject matter of the pending application:

Dr. Holodniy stated that he was until the summer of 1991 a research fellow in the

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[16] In May 1991, Stanford submitted an article to the Journal of Clinical Investigation entitled "Reduction in Plasma Human Immunodeficiency Virus Ribonucleic Acid after Dideoxynucleoside Therapy as Determined by the Polymerase Chain Reaction" (the JCI Article"). Chiang Decl., Ex. 25. The named authors include Holodniy, Katzenstein, and Merigan from Stanford. *Id.* Stanford identified no Cetus employees as authors, and there is no evidence that Stanford sought approval from Cetus to publish this article. The article describes (with insubstantial differences) the same assay that was disclosed in the JID Article, including: (1) extraction of HIV RNA from a patient sample; (2) reverse transcription of the HIV RNA; (3) amplification of target DNA using Cetus information and materials taught to Holodniy; (4) detection of the targeted DNA using the HRP probe; and (5) quantitation of the virus in the sample using the standard designed and constructed by Cetus. Chiang Decl., Ex. 25 (JCI Art.) at PENNIE 001219-1220. As Holodniy admitted at deposition, the JCI Article describes results of HIV quantitation experiments using the HIV RNA Quantitation Assay developed at Cetus. Chiang Decl., Ex. 46 (Holodniy Dep.) at 335:23-336:17, 338:24-340:2, 341:25-342:3, 343:5-344:13, 345:24-347:10.

[17] The '730 Patent specifically states that: "Serum may be used interchangeably with plasma according to the invention." '730 Patent, col. 4, ll. 8-10.

> Division of Infectious Disease at Stanford University. His inventive contribution to the subject matter of the present application occurred (sic) during this period, and principally concerns quantitation of HIV RNA in plasma of AIDS patients.

Chiang Decl., Ex. 29 at STAN 6336 (emphasis added). In other words, Holodniy's contribution to the subject matter of the patent application, which entitled him to be named as an inventor, was the very work that he acknowledges he did at Cetus.

Holodniy's once-privileged correspondence with patent counsel confirms this. In an August 1992 letter describing his contributions to the subject matter of the application, Holodniy made clear that the work disclosed in the application which entitled him to inventor status was the very work reflected in the JID Article--namely the development of the HIV RNA Quantitation Assay. Chiang Decl., Ex. 26. in

During prosecution, Stanford repeatedly relied on the Cetus/Stanford joint work in an effort to obtain allowance. In particular, the Examiner repeatedly rejected the application on the

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[18] Stanford inventor Katzenstein also admitted at deposition that the "JID article is the fulfillment of that idea [of measuring HIV RNA to monitor therapy] through a whole series of technical assay development issues that went on over perhaps two years" and that the "JID article is the first description . . . of all of the technical requirements to achieve measurement of HIV RNA in the plasma using a PCR reaction." Chiang Decl., Ex. 49 (Katzenstein Dep.) at 61:20-62:15, 90:16-91:6. Subsequent researchers have recognized that the techniques described in this article also describe the quantification of HIV RNA from plasma. Chiang Decl., Ex. 24 (Saag Art.); Ex. 23 (Kuritzkes Art.).

basis of 35 U.S.C. §§ 102 and 103 prior art, and Stanford attempted to distinguish this art on two primary grounds: (1) the references did not disclose using serum or plasma --which was referred to interchangeably during prosecution of the patent--as the starting material for PCR;[19] and (2) the prior art references disclose detection rather than quantitation of HIV RNA.[20] In other words, to obtain allowance, Stanford relied on Cetus and Holodniy's joint work.

Subsequently, U.S. Patent No. 6,503,705, a continuation of the '730 Patent, issued on January 7, 2003. *See* Chiang Decl., Ex. 28. The '705 Patent is also entitled "Polymerase Chain Reaction Assays for Monitoring Antiviral Therapy and Making Therapeutic Decisions in the Treatment of Acquired Immunodeficiency Syndrome," relies on a virtually identical specification as the '730 Patent, and lists Merigan, Katzenstein, and Holodniy as inventors. *Id.*

E. Cetus's PCR Business is Acquired By Roche

Under a 1991 Assets Purchase Agreement ("APA"), Hoffmann-La Roche, Inc. purchased all of Cetus's PCR assets--the entirety of Cetus's PCR business. Chiang Decl., Ex. 44 (Assets Purchase Agreement) at RMS 6318 (Preamble), RMS 6333-6334 (Transferred assets). The PCR assets purchased by Hoffmann-La Roche comprised of Cetus's PCR-related technology and business, including: Personal Property; listed PCR Intellectual Property; Cetus's rights under Transferred Contracts; and Cetus's rights under any confidentiality agreements. *Id.* at § 2.1(a)-(g).

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[19] *See, e.g.,* Chiang Decl., Ex. 38 at STAN 1433 ("None of the references cited by the Examiner specifies that the PCR reaction be performed on a serum sample."); *id.* at STAN 1434 ("There is no suggestion to perform PCR analysis on patient serum samples generated in vivo." (emphasis in original)); *id.* ("Cantin does not suggest PCR analysis on patient serum samples to assess anti HIV therapy" (emphasis in original)); *id.* at STAN 1435 ("Hart does not utilize serum samples for their PCR detection." (emphasis in original)); *id.* ("Therefore, taken as a whole, the references cited by the Examiner do not suggest . . . using . . . HIV nucleic acid in a serum sample from a patient"); Ex. 39 at STAN 000997 ("the methods of this invention utilize specific PCR parameters . . . to identify the presence of, or specific recited levels of, HIV sequences in plasma"); *id.* at STAN 001008 ("There is, however, no disclosure in Hart of any serum HIV detection methodology or any description, much less an enabling description, as to how to detect HIV sequences by PCR from serum samples." (emphasis in original)).

[20] *See, e.g.*, Chiang Decl., Ex. 39 at STAN 000997 ("the methods of this invention utilize specific PCR parameters . . . to identify the presence of, or specific recited levels of, HIV sequences"); *id.* at STAN 001000 ("the determination of specific levels of HIV sequences such as HIV RNA copy numbers"); *id.* at STAN 1013-14 (Ottmann limited to detection; it does not describe quantitation).

In addition, Hoffmann-La Roche, also purchased license rights to any intellectual property used in the PCR Business that was not listed as transferred intellectual property. *Id.* at § 2.8(b).

The schedules to the APA included "Transferred Intellectual Property" and "Transferred Contracts." Chiang Decl., Ex. 44 (Assets Purchase Agreement) at RMS 6444-6547. As set forth in those schedules, Transferred Intellectual Property includes: (1) the invention disclosure submitted by Cetus scientist Michael Konrad on behalf of Mark Holodniy (*Id.* at RMS 06460) ("Invention Disclosure 90-003 Quant of HIV DNA, Konrad"); and (2) "All PCR Technology. . . . that is contained in the following documents to the extent of Seller's [Cetus] interest: . . . all files, book and records and laboratory notebooks of the PCR Business. . . . " (*Id.* at RMS 06464). The schedule of Transferred Contracts also includes: (1) Holodniy's February 14, 1989 Visitor's Confidentiality Agreement (*Id.* at RMS 06481); and (2) the MTA (*Id.* at RMS 06524) at issue here. Hoffmann-La Roche's rights were subsequently transferred to Roche Molecular Systems on January 1, 1997. Chiang Decl., Ex. 30 (transfer agreement).

The cRNA standard used in the HIV RNA Quantitation Assay, CC2, was transferred from Cetus to Roche and has not been commercially available. Nersesian Decl., ¶¶ 3-10, Exs. 1-5. The plasmid strain that is the master copy for the CC2 cRNA standard, pCC2, was transferred specifically to Roche and is identified in Roche's current culture collection as "Positive control used in HIV quantification." *Id.*, ¶ 4, Ex. 1.

Procedural Posture

Despite the parties' agreements relating to the development of the HIV RNA Quantitation Assay, on October 14, 2005, Stanford sued Roche for infringement of the '705 and '730 Patents. In particular, Stanford accuses Roche's Amplicor HIV test of infringement.

In response to Stanford's Complaint, Roche asserted, among other things, affirmative defenses claiming that: (1) Roche owns, at a minimum, a pro rata share in the patents pursuant to the assignment clause in Holodniy's 1989 Visitor Agreement; (2) Roche has shop rights to the patents due to the joint work conducted between Cetus and Holodniy and Stanford; (3) Roche is entitled to a royalty-free, non-exclusive license under the MTA; and (4) due to the assignment

provision in Holodniy's Visitor Agreement, Stanford lacks standing to assert the '730 and '705 Patents.

Argument

I. ROCHE IS ENTITLED TO SUMMARY JUDGMENT ON ITS AFFIRMATIVE DEFENSES RELATING TO OWNERSHIP AND LICENSE PURSUANT TO THE VISITOR AGREEMENT, SHOP RIGHTS, AND THE MTA

To prevail on summary judgment, Roche, as the moving party, must demonstrate "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law" with respect to its ownership claims and defenses. Fed. R. Civ. P. 56(c); *Celotex. Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-50 (1986). Mere disagreement, or the bald assertion that a genuine issue of material fact exists, does not preclude the grant of summary judgment. *See Harper v. Wallingford*, 877 F.2d 728, 731 (9th Cir. 1989). A scintilla of evidence opposing summary judgment is insufficient to create a genuine issue of material fact and thus cannot preclude summary judgment. *Liberty Lobby*, 477 U.S. at 252. Here, because Stanford's, Merigan's, and Holodniy's admissions conclusively establish that Roche is entitled to ownership of, or, at a minimum, license to, the '730 and '705 Patents pursuant to the parties' agreements, summary judgment in favor of Roche should be granted on Roche's affirmative defenses.[21]

II. DR. HOLODNIY'S VISITOR AGREEMENT GIVES ROCHE AN OWNERSHIP INTEREST IN THE '730 AND '705 PATENTS

Under California law, the analysis of an agreement must begin with its plain language. *See Cal. Civ. Code* § 1638 (2005) ("The language of a contract is to govern its interpretation, if the language is clear and explicit, and does not involve an absurdity."); *Wilson v. Gentile*, 8 Cal. App. 4th 759, 762, 10 Cal. Rptr. 2d 713, 714 (1992) ("We begin by analyzing the logical

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[21] Although Stanford has expressed its intention to move for summary judgment based on the statute of limitations, under controlling precedent, the statute of limitations cannot bar Roche's ownership and license defenses to Stanford's patent infringement action because "statutes of limitations do not apply to defenses." *Styne v. Stevents*, 26 Cal.4th 42, 51-52 (2001); *accord United States v. Western Pacific R.R. Co.*, 352 U.S. 59, 71-72 (1956).

interpretation of the . . . clause applying the primary definitions of the word[s] and the ordinary rules of grammar."). When a contract's terms are unambiguous, the court must determine the meaning of the contract as a matter of law solely through an examination of the language of the contract. *Cal. Civ. Code* § 1638. *Shaw v. Regents of the Univ. of Cal.*, 58 Cal. App. 4th 44, 53 (1997) ("Where contract language is clear and explicit and does not lead to absurd results, we ascertain the intent from the written terms and go no further") (quotation omitted). Here, the Visitor Agreement is short and clear, and Stanford cannot dispute that whatever work Holodniy did in connection with the development of the HIV RNA Quantitation Assay, it is covered by that agreement.

A. The Development Of The HIV RNA Quantitation Assay Falls Under The Visitor Agreement

It cannot be disputed that Holodniy executed the Visitor Agreement in February 1989 as a condition of being allowed access to Cetus. *See supra* at 8. The Visitor Agreement's provision governing Cetus's rights in any "ideas, inventions, or improvements" is short and clear. Namely, it provides, in relevant part, that should Holodniy create inventions as a result of his access to Cetus, he "hereby" assigns them to Cetus:

> 3. If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual or anticipated business of CETUS, I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph.

Chiang Decl, Ex. 11.

Stanford cannot dispute that, whatever contribution Holodniy made to the HIV RNA Quantitation Assay, such contribution was made "as a consequence of [Holodniy's] access to Cetus' facilities or information." Holodniy's deposition testimony made that absolutely clear. *See supra* at 12-13. Nor can Stanford dispute that Holodniy admits that his contributions to the subject matter of the '730 and '705 Patents are related to his alleged contributions to the development of

the HIV RNA Quantitation Assay.[22] As the named inventors represented to the PTO, in no uncertain terms: "[Holodniy's] inventive contribution to the subject matter of the present application . . . principally concerns the quantitation of HIV RNA in plasma of AIDS patients." Chiang Decl., Ex. 29 (Elledge Declaration) at 2. As Holodniy confirmed in a letter to his patent lawyer,[23] his inventive contribution to the subject matter of the patent related to the quantification of HIV using plasma which, in turn, related to the body of work published in the JID Article. Chiang Decl., Ex. 26 (Holodniy letter). Stanford cannot dispute this because Holodniy's unqualified and legion admissions prevent it: namely, use of the HIV RNA Quantitation Assay was described in the JID Article co-published with Cetus, was the subject of a Cetus invention disclosure, and its development resulted from Holodniy's unfettered access to Cetus material, know-how, equipment, and information. *See supra* at 12-16.

Holodniy received his end of the bargain when, pursuant to the Visitor Agreement, he was permitted unfettered access to Cetus's cutting edge technology concerning the use of PCR to quantitate HIV RNA. Based on this access, Holodniy has built his career. In exchange for this access, Cetus, now Roche, received an ownership interest in the '730 and '705 Patents. Accordingly, summary judgment in favor of Roche is warranted.

B. Controlling Law Provides That Holodniy's Contract Assigned His Patent Rights To Cetus

Once the HIV RNA Quantitation Assay was completed at Cetus, the Visitor Agreement,

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[22] The inventions claimed in the '730 and '705 Patents refer to using a PCR assay to quantitate the amount of HIV in a sample. If the amount of HIV in a given patient's sample decreases over time, that may suggest that a therapy is working; and vice versa. *See* '730 Patent, 1:17-24; '705 Patent, 1:21-28. This is precisely the technique set forth in the JID Article co-published by Cetus and Stanford. The JID Paper teaches a PCR assay used to measure the quantity of HIV (which, according to Holodniy's letter to Stanford's patent counsel, was the same assay set forth in the patent) and expressly states that the assay may be used to monitor HIV therapy. Chiang Decl., Ex. 22 (JID Art.); *see id.* Ex. 26 (Holodniy letter).

[23] In this lawsuit, Stanford initially withheld this 1992 contemporaneous letter from Holodniy to Stanford's counsel as privileged, despite Stanford waiving the attorney client privilege by making affirmative statements in the prosecution history about conversations between Stanford's patent lawyers and the named inventors. Only after Roche moved to compel, and this Court ordered that Stanford had waived privilege, did Stanford produce this crucial document. *See* Dkt. No. 63.

which expressly provided that Holodniy "will assign *and do hereby assign* to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph," provided for the immediate assignment of Holodniy's legal interest in that invention to Cetus. Chiang Decl., Ex. 11 at ¶ 3. Such an assignment gives the assignee an undivided interest in the entire invention and the resulting patent. *Eli Lilly and Co. v. Aradigm Corp.*, 376 F.3d 1352, 1357 n. 2 (Fed. Cir. 2004) ("The district court correctly held that Dr. DiMarchi's status as a co-inventor of the invention in claim 6 entitled Lilly, as the assignee of Dr. DiMarchi's interest, to the rights of a co-owner of the entire '477 patent."). Holodniy's assignment of an "expectant interest" is valid and enforceable. *See Filmtec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991).

In *Filmtec*, the inventor of the patent-in-suit was employed at a research company until 1977 doing research for the government under a contract that provided that the company "agrees to grant and does hereby grant to the Government the full and entire domestic right, title and interest in [any inventions . . . made in the course of or under this contract or any subcontract (of any tier) thereunder]." *Id.* at 1570 (alterations in original). In 1978, the inventor left the company and formed FilmTec. *Id.* In 1979, the inventor filed for the patent with FilmTec as the assignee. *Id.* FilmTec then sued Allied-Signal. *Id.* Allied-Signal, however, argued that the inventor had already assigned the invention to his former company in his employment contract, and the company in turn had assigned the invention to the U.S. Government. *Id.*

The Federal Circuit held: "If an assignment of rights in an invention is made prior to the existence of the invention, this may be viewed as an assignment of an expectant interest. An assignment of an expectant interest can be a valid assignment." *Id.* at 1572 (citing *Mitchell v. Winslow*, 17 Fed. 527, 531-32 (C.C.D. Me. 1843)). The Federal Circuit stated:

> In our case, the contract between [former company] and the Government did not merely obligate [former company] to grant future rights, but expressly granted to the Government [former company]'s rights in any future invention. Ordinarily, *no further act would be required once an invention came into being*; the transfer of title would occur by operation of law. If a similar contract provision existed between [inventor] and [former company] . . ., and if the invention was made before [inventor] left [former company]'s employ . . ., *[inventor] would have no rights in the invention or any ensuing patent to assign to Filmtec.*

Id. at 1573 (emphasis added). Similarly, like the contract in *Filmtec*, Holodniy's contract immediately assigned any expectant patent rights to Cetus.

More recently, in *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000), the Federal Circuit reiterated the *Filmtec* rule. In *Speedplay*, the issue was whether the plaintiff, a California company, owned the patent (invented by its employee Bryne) pursuant to an assignment clause in the employment contract. *Id.* The Federal Circuit applied *Filmtec* to the California employment contract and found that the assignment clause had automatically assigned the entire patent. *Id.* ("Speedplay argues that it automatically obtained title to the '894 patent pursuant to the [employment agreement]. We agree."). *Speedplay* also made clear that the *Filmtec* framework is not limited to employment arrangements, but applies to contractor/client arrangements as well. *Id.* (characterizing *Filmtec* as a case where "the contractor agreed 'to grant and does hereby grant'" to the client the rights and title to any invention, whether patentable or not").

Here, the situation is in all material respects identical to *Filmtec* and *Speedplay*. Holodniy executed an assignment to Cetus in 1989. Once the invention was made "no further act would be required . . . the transfer of title would occur by operation of law." *Id.* (quoting *Filmtec*, 939 F.2d at 1573). Accordingly, because Holodniy's rights in the '730 and '705 Patents resulted as a consequence of his access to Cetus facilities and information, and Holodniy admitted that his inventive contribution was set forth in the Cetus/Stanford JID Article, those rights were transferred to Cetus by operation of law under the terms of the Visitor Agreement. Thus, because it cannot be disputed that Roche acquired Cetus' rights in Holodniy's "invention," summary judgment in favor of Roche is now appropriate.

C. Roche acquired Cetus's rights in the patents

Section 2.1(d) of the Assets Purchase Agreement between Hoffmann-La Roche and Cetus transferred from Cetus to Hoffmann-La Roche "[a]ll of Seller's Rights (including deposits related thereto) under Contracts listed on Schedule 2.1(d) (the "Transferred Contracts"). Chiang Dec., Ex. 44. The Assets Purchase Agreement closed on December 11, 1991 transferring all assets to

Hoffmann-La Roche. *Id.* The 1989 Visitor Agreement with Holodniy is expressly listed in Schedule 2.1(d). *Id.* at RMS 6481. Accordingly, Cetus's rights in the patents-in-suit, deriving from the Holodniy contract, were transferred to Hoffmann-La Roche by the plain terms of the Assets Purchase Agreement, including ownership rights in the patents-in-suit. Those rights were later transferred to Roche Molecular Systems. Chiang Decl., Ex. 30 (assignment to RMS).

III. ROCHE HAS A "SHOP RIGHTS" LICENSE TO THE PATENTS

A "shop right" is a "right that is created at common law, when the circumstances demand it, under principals of equity and fairness, entitling an employer to use without charge an invention patented by one or more of its employees without liability for infringement." *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993). Although "shop rights" are usually found in employer/employee relationships, the Federal Circuit has held that "shop rights" are not confined to employees and apply also to independent contractors as well. *Id.* at 1583, n.15.

The "proper methodology for determining whether an employer has acquired a 'shop right' in a patented invention is to look to the totality of the circumstances. . . . One should look to such factors as the circumstances surrounding the development of the patented invention and the inventor's activities respecting that invention, once developed, to determine whether equity and fairness demand that the employer be allowed to use that invention in his business." *Id.* at 1581-82. In particular, "[a]n employer *will* have shop rights in an invention in situations where the employer has financed an employee's invention by providing wages, materials, tools and a work place." *Id.* at 1582 (emphasis added).

It is black letter law that the holder of a shop right is entitled to "duplicate it [the invention] as often as he may find occasion to employ similar appliances in his business." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 189 (1933). This includes the right to sell the invention. *Flannery Bolt Co. v Flannery*, 86 F.2d 43 (3d Cir. 1936); *Withington-Cooley Mfg. Co. v Kinney*, 68 Fed. 500 (6th Cir. 1895); *Ralph J. Gonnocci Revocable Living Trust v. Three M Tool & Mach.*, 2006 WL 1676898 at *3 (E.D. Mich. 2006) (applying shop rights on summary judgment including right to sell).

A. Cetus obtained shop rights to Holodniy's and Stanford's work

As detailed extensively in Section C. 3., *supra*, the undisputed evidence demonstrates that whatever contribution Holodniy made to the HIV RNA Quantitation Assay, he made as a result of his access to Cetus equipment, Cetus materials, Cetus information, and his collaboration with Cetus's PCR experts. As discussed above, Holodniy received voluminous Cetus materials such as the cRNA standard developed by Cetus scientists Alice Wang and Clayton Casipit, as well as biological materials and reagents such as the HRP-labeled probe, which Holodniy brought back to the Stanford lab. See, e.g., Chiang Decl., Ex. 46 (Holodniy Dep.) at 72:7-19, 172:7-19, 174:21-175:5, 187:21-188:5, 190:19-21, 191:20-25, 215:23-216:6, 256:11-258:5, 258:10-259:5, 329:14-22. Holodniy also admits he received information from Cetus. *Id.* at 158:4-19 (quantitating the input and output of DNA), 166:21-167:25 (feasibility of quantitation), 170:20-171:6 (RNA extraction), 172:20-24 (reverse transcription), 177:3-22 (protocol for extraction and reverse transcription of RNA from serum), 180:14-25 (reverse transcription and extraction), 182:4-9 (amplification), 185:5-14 (isotopic detection of PCR products), 192:24-194:20 (advice and suggestions regarding quantitation standard), 198:10-200:25 (strategy for construction of standard), 202:4-20 (identifying primers to order), 203:22-204:14 (constructing a mutant gag gene sequence), 211:24-212:10 (colorimetric detection), 246:21-247:10 (techniques related to cellular DNA and RNA and serum RNA quantitation), 254:5-255:7 (extraction procedures for extraction of RNA), 286:1-10 (avidin-biotin protocol). Holodniy himself wrote a retrospective article in 2006 to commemorate the publication of the JID Paper--the paper he co-authored with Cetus--which has become one of the most cited papers in the history of the Journal of Infectious Diseases. In this retrospective article, Holodniy celebrates Cetus and describes Holodniy's daily commute from Stanford to Cetus to learn from Cetus scientists. Chiang Decl., Ex. 9.

Cetus opened its doors to Holodniy and Stanford. Now, however, Holodniy and Stanford seek to sue Cetus's successor-in-interest for infringement of patents involving subject matter that was developed at Cetus, using Cetus's equipment, materials, technical information, and Cetus's know-how. Thus, this is a prototypical case for the application of shop rights. *McElmurry*, 995 F.2d at 1580; *see also Dubilier*, 289 U.S. at 188-89 ("Since the servant uses his master's time,

facilities, and materials to attain a concrete result, the latter is in equity entitled to use that which embodies his own property.").

B. Roche Acquired Cetus's Shop Rights

Shop rights "may be transferred in connection with a sale and continuation of the entire business to which the shop right originally attached." 8 Chisum on Patents § 22.03[3][c] (citing *Lane & Bodley Co. v. Locke*, 150 U.S. 193 (1893)). It cannot be disputed that Roche acquired the entirety of Cetus's PCR business. *See* Chiang Decl., Ex. 44 (Asset Purchase Agreement) at RMS 6318 (Preamble); Ex. 50 (Ostrach Dep.) at 17:25-20:9. Accordingly, this necessarily included the shop rights.

IV. ROCHE HAS A ROYALTY-FREE LICENSE TO THE '730 AND '705 PATENTS PURSUANT TO THE MTA BETWEEN STANFORD AND CETUS

Independent of the ownership rights that Roche acquired as a result of Cetus's contract with Holodniy, Roche also acquired a non-exclusive royalty-free license to the '730 and '705 Patents under the MTA.[24] The MTA was executed by Stanford, as well as Merigan and Schwartz, and it was offered in response to Merigan's request that Cetus provide him with Cetus's detailed PCR protocols. *See* Groves Decl., ¶ 10.

The MTA stated that Cetus would provide to Merigan, Schwartz and their co-workers "oligonucleotide primers and probes" and "control dilutions of HIV" and "associated PCR technology" and "any related biological material or associated know-how and data." Chiang Decl., Ex. 10 (MTA). In return for this extraordinary supply of materials and know-how (back when PCR was in its infancy), the MTA provided that Cetus "shall be free to use" data and information that result from Stanford's research related to the materials. Id., ¶ 7.

Consistent with Cetus's right to freely use any data or results related to the materials provided to Stanford, the MTA further provided that if such "Materials" are used to create anything that is commercially useful, Merigan and Schwartz and Stanford agreed that "[i]n consideration of CETUS' providing of the Material, INSTITUTION, to the extent it is legally able

[24] As described in section E., *supra*, the MTA was specifically transferred from Cetus to Roche under the Assets Purchase Agreement.

to do so, hereby grants CETUS the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith based on the respective parties' contributions and relevant industry standards, to use commercially the invention or substance, *or at CETUS' option, a nonexclusive license.*" *Id.* at ¶ 8 (emphasis added).

Just days after the execution of the MTA, Holodniy was sent by Merigan to Cetus to learn PCR. As set forth above in Section C. 3., *supra*, over a nine month period Holodniy was provided with information, protocols, know-how, reagents, and other biological material covered by the unambiguous definition of "Materials" in the agreement. For instance, it cannot be disputed that Holodniy received the cRNA standard for quantification created and validated by Cetus scientists Alice Wang and Clayton Casipit. It cannot be disputed that this know-how and material was used by Holodniy and Stanford in conjunction with the development at Cetus of the HIV RNA Quantitative Assay that provided the basis for Holodniy's alleged contributions to the subject matter of the '730 and '705 Patents. *See* Section D., *supra*. Accordingly, such use resulted in a "first option to an exclusive license, at a reasonable royalty . . . *or at CETUS' option, a nonexclusive license.*" Chiang Decl., Ex. 10, ¶ 8.

Here, the phrase "at a reasonable royalty to be negotiated in good faith based on the respective parties' contributions and relevant industry standards, to use commercially the invention or substance," clearly modifies the immediately preceding language, i.e. the "exclusive license" and not the language following, i.e. "*or at CETUS' option, a nonexclusive license.*" Thus, Cetus was entitled, at a minimum, to an immediate, royalty-free, non-exclusive license or it could negotiate for an exclusive license subject to a reasonable royalty. To read the clause any other way would render the distinction between an exclusive and a nonexclusive license entirely meaningless and would ignore the rule that the "whole of a contract is to be taken together, so as to give effect to every part." Cal. Civ. Code § 1641. *See TIG Ins. Co. of Michigan v. Homestore, Inc.*, 137 Cal. App. 4th 749, 757 (2006); *Ticor Title Ins. Co. v. Rancho Santa Fe Ass'n*, 177 Cal. App. 3d 726, 730, 223 Cal. Rptr. 175, 177 (1986); *Bush v. Cal. Conservation Corps*, 136 Cal. App. 3d 194, 202 (1982); *Bayview Hunters Point Community Advocates v. Metropolitan Transp. Com'n*, 366 F.3d 692, 700 (9th Cir. 2004).

This reading is fully consistent with the intent of the agreement as determined from its plain language. Under the contract, Cetus was to (and did) provide confidential and proprietary material to Stanford scientists. Given the state of the technology, that "Material" had real economic value. The MTA is explicit that Cetus is "free to use" the results of Stanford's research "for any purpose." Thus, in return, i.e. "in consideration," for the material, Stanford agreed to give Cetus something of value, a royalty-free non-exclusive license to any invention created using the material with the first option of making the license a royalty-bearing exclusive license if Cetus so desired. These agreements were designed to protect Cetus, to prevent an institution or anyone else that received confidential and proprietary information from Cetus from blocking Cetus's access to an invention created using that material. The automatic provision of a non-exclusive royalty-free license was the means by which to accomplish that intent.

The common sense interpretation and the clear intent reflected by the agreement is also confirmed by the uncontradicted extrinsic evidence regarding whether the non-exclusive license would be royalty bearing. The only evidence in the record of a communicated intent regarding nonexclusive licenses is that of Cetus's General Counsel Michael Ostrach, who testified that he informed the Stanford Sponsored Projects Office that Cetus understood that no payment would be required for a nonexclusive license under this negotiated language. Chiang Decl., Ex. 50 (Ostrach Dep.) at 91:21-94:16.

V. STANFORD HAS FAILED TO PROVE IT HAS STANDING TO SUE

Stanford bears the burden of proving that it is the sole and exclusive owner of the patents asserted against Roche. *Sicom Sys. v. Agilent Techs.*, 427 F.3d 971, 976 (Fed. Cir. 2005) ("The party bringing the action bears the burden of establishing that it has standing."). The standing doctrine requires that *every* owner of a patent must be joined as a plaintiff in a patent infringement suit. *Prima Tek, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1377 (Fed. Cir. 2001); *Ethicon, Inc., v. U.S. Surgical Corp.*, 135 F.3d 1456, 1466 (Fed. Cir. 1998). Stanford thus bears the burden of proving Roche's lack of ownership in order to sue Roche for infringement. *See Filmtec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991) ("[T]he issue here is not whether title lies in the Government or some other third party; it is rather whether FilmTec has made a sufficient showing

to establish reasonable likelihood of success on the merits, which includes a showing that title to the patent and the rights thereunder are in FilmTec."). Therefore, because the undisputed facts show that Roche is entitled to an ownership interest in the patents, Stanford has necessarily failed to carry its burden of proving its standing to sue and its infringement case must be dismissed.

Conclusion

For the foregoing reasons, Roche respectfully requests that its Motion for Summary Judgment of Ownership of and License to the '730 and '705 Patents be granted in its entirety.

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Respectfully submitted,

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