

# Exhibit 26

PAUL VOLBERDING, M.D.

08/19/07

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIATHE BOARD OF TRUSTEES OF THE  
LELAND STANFORD JUNIOR  
UNIVERSITY,

Plaintiff,

vs.

No. C-05-04158-MHP

ROCHE MOLECULAR SYSTEMS, INC.,  
et al.,

Defendants.

AND RELATED COUNTERCLAIM.

DEPOSITION OF PAUL VOLBERDING, M.D.  
Palo Alto, California  
Sunday, August 19, 2007Reported by:  
GINA GLANTZ  
CSR No. 9795, RPR, RMR  
JOB No. 3-70580

## 1 APPEARANCES:

2

3

For Plaintiff Stanford University and Counterclaim

Defendants Tom Merigan and Mark Holodniy:

4

COOLEY GODWARD KRONISH LLP

5

BY: MICHELLE S. RHYU, Ph.D.

6

Attorney at Law

7

3000 El Camino Real

8

Five Palo Alto Square, 4th Floor

9

Palo Alto, California 94306-2155

10

(650) 843-5505

11

For the Roche Defendants:

12

QUINN EMANUEL URQUHART OLIVER &amp; HEDGES, LLP

13

BY: BRIAN C. CANNON

14

Attorney at Law

15

555 Twin Dolphin Drive, Suite 560

16

Redwood Shores, California 94065-2139

17

(650) 801-5000

18

Videographer:

19

RAY TYLER

20

SARNOFF COURT REPORTERS AND LEGAL TECHNOLOGIES

21

450 Sansome Street, Suite 1550

22

San Francisco, California 94111

23

(415) 274-9977

24

25

Page 3

1 UNITED STATES DISTRICT COURT  
2 NORTHERN DISTRICT OF CALIFORNIA3  
4 THE BOARD OF TRUSTEES OF THE  
5 LELAND STANFORD JUNIOR  
6 UNIVERSITY,

Plaintiff,

7 vs.

No. C-05-04158-MHP

8 ROCHE MOLECULAR SYSTEMS, INC.,  
9 et al.,

10 Defendants.

11  
12 AND RELATED COUNTERCLAIM.  
13  
14  
1516 Deposition of PAUL VOLBERDING, M.D., taken  
17 on behalf of Roche Defendants, at 3000 El Camino Real,  
18 Five Palo Alto Square, 4th Floor, Palo Alto, California,  
19 beginning at 10:10 a.m. and ending at 3:40 p.m., on  
20 Sunday, August 19, 2007, before GINA GLANTZ, Certified  
21 Shorthand Reporter No. 9795.  
22  
23  
24  
25

Page 2

## 1 INDEX

2 WITNESS

EXAMINATION

3 PAUL VOLBERDING, M.D.

4

5

BY MR. CANNON

8, 154

6

7

BY MS. RHYU

164

8

9

## EXHIBITS

10

DEPOSITION

PAGE

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

95

96

97

98

99

100

101

102

103

104

105

106

107

108

109

110

111

112

113

114

115

116

117

118

119

120

121

122

123

124

125

126

127

128

129

130

131

132

133

134

135

136

137

138

139

140

141

142

143

144

145

146

147

148

149

150

151

152

153

154

155

156

157

158

159

160

161

162

163

164

165

166

167

168

169

170

171

172

173

174

175

176

177

178

179

180

181

182

183

184

185

186

187

188

189

190

191

192

193

194

195

196

197

198

199

200

201

202

203

204

205

206

207

208

209

210

211

212

213

214

215

216

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243

244

245

246

247

248

249

250

251

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

PAUL VOLBERDING, M.D.

08/19/07

11:08:57 1 Q Okay. We're going to turn to more of a  
 11:09:01 2 definitional topic now. HIV is a retrovirus; correct?  
 11:09:07 3 A Are you asking me to refer to a document?  
 11:09:10 4 Q No, I'm not. At the moment, I'm not asking you  
 11:09:11 5 to refer to a document, so you can set those aside.  
 11:09:17 6 You understand that HIV is a retrovirus; is  
 11:09:21 7 that right?  
 11:09:21 8 A That's right.  
 11:09:23 9 Q And that means its genetic material is in the  
 11:09:26 10 form of RNA; is that right?  
 11:09:28 11 A That's part of the definition, yes.  
 11:09:30 12 Q What's the remainder of the definition?  
 11:09:32 13 A Well, retroviruses employ a reverse  
 11:09:37 14 transcriptase to copy their genetic material. They  
 11:09:42 15 integrate that genetic material into the host cell and  
 11:09:47 16 are then reproduced by the cell.  
 11:09:50 17 Q And the reproduction by the cell involves  
 11:09:53 18 forward transcription; right?  
 11:09:55 19 A That's part of the -- that's one of the steps,  
 11:09:58 20 yes.  
 11:09:58 21 Q And then there's -- and then there's an  
 11:10:01 22 assembly step; right?  
 11:10:02 23 MS. RHYU: Objection. Vague.  
 11:10:03 24 THE WITNESS: Those are -- that's another step,  
 11:10:08 25 yes.

Page 45

11:12:19 1 that sense, the replication of the genome of the virus.  
 11:12:23 2 Q Are you pointing out a particular sentence in  
 11:12:26 3 your declaration? Perhaps you could point me to it.  
 11:12:44 4 A On page 6, in paragraph 16, line 27, in which  
 11:13:01 5 I'm referring to reverse transcription.  
 11:13:03 6 Q So could you just clarify your testimony with  
 11:13:11 7 respect to the sentence? I'll just read it, "Further,  
 11:13:16 8 antiretroviral agents are not limited to drugs effective  
 11:13:19 9 in reducing or stopping the genome 'replication' step."  
 11:13:24 10 What is it you're trying to clarify?  
 11:13:25 11 A Just that the way -- as I look at this, after I  
 11:13:31 12 wrote it, I realize that replication would generally  
 11:13:36 13 refer to the entire reproduction of the entire virus,  
 11:13:41 14 but replication, in this sense, I was using as copying,  
 11:13:45 15 which is a common use of the term as well. So it is  
 11:13:50 16 reverse transcription, it's just not the language that I  
 11:13:53 17 would usually use.  
 11:13:56 18 Q Now, the nucleoside analogs were the first  
 11:14:08 19 antiretroviral therapies; correct?  
 11:14:16 20 MS. RHYU: Objection. Vague as to  
 11:14:20 21 "antiretroviral therapies."  
 11:14:22 22 THE WITNESS: The nucleoside analogs were the  
 11:14:27 23 first compounds shown to be effective in inhibiting the  
 11:14:38 24 virus in patients with HIV infection, but other agents  
 11:14:42 25 had been -- other antiretroviral agents had been looked

Page 47

11:10:09 1 BY MR. CANNON:  
 11:10:09 2 Q Is it fair to say that one of the goals of  
 11:10:17 3 antiretroviral therapy is to halt the life cycle of HIV?  
 11:10:21 4 MS. RHYU: Objection. Vague, lacks foundation,  
 11:10:25 5 calls for speculation.  
 11:10:25 6 THE WITNESS: It's fair to say that  
 11:10:31 7 antiretroviral therapy is designed to slow the growth of  
 11:10:36 8 the virus.  
 11:10:39 9 BY MR. CANNON:  
 11:10:46 10 Q Do you recall when was the first time you put a  
 11:10:50 11 patient on antiretroviral therapy?  
 11:11:03 12 A I don't recall a specific patient or a specific  
 11:11:09 13 date, but I put patients on retroviral therapy in 1986  
 11:11:20 14 certainly, and maybe before that, but certainly in 1986.  
 11:11:28 15 Q Do you recall the antiretroviral therapy that  
 11:11:31 16 you put a patient on as early as 1986?  
 11:11:34 17 A The first specifically antiretroviral agent  
 11:11:45 18 that I used, I believe, was AZT.  
 11:11:48 19 Q That's a nucleoside analog; right?  
 11:11:51 20 A Yes, it is.  
 11:11:51 21 Q That inhibits reverse transcription?  
 11:11:55 22 A Yes, it does. And I believe in my declaration,  
 11:12:10 23 I was a little confused in my terminology. It inhibits  
 11:12:10 24 the replication of the genome, which is not a term that  
 11:12:15 25 I would usually use, but it inhibits the copying or, in

Page 46

11:14:45 1 at in the laboratory at that time, or maybe even before.  
 11:14:49 2 BY MR. CANNON:  
 11:14:49 3 Q It's fair to say that a lot of agents were  
 11:14:54 4 looked at but only a limited number actually  
 11:14:58 5 demonstrated clinical value?  
 11:14:59 6 A That's true.  
 11:15:04 7 Q And that's true throughout the years up to the  
 11:15:06 8 present day; correct?  
 11:15:07 9 A Could you restate that?  
 11:15:10 10 Q It's true that even up to today, there's a lot  
 11:15:15 11 of agents that are possibilities but only a limited  
 11:15:17 12 number actually end up having clinical value?  
 11:15:20 13 A That's true.  
 11:15:21 14 Q Do you recall when was the first time you put a  
 11:15:28 15 patient on therapy when that therapy was not a  
 11:15:31 16 nucleoside analog?  
 11:15:41 17 A I don't recall which clinical trials I was  
 11:15:46 18 involved with at the time, but nonnucleosides and  
 11:15:50 19 protease inhibitors were entering clinical trials in  
 11:15:53 20 1990, 1991, and I might very well have participated in  
 11:15:57 21 those trials.  
 11:15:58 22 Q Do you know for a fact whether you participated  
 11:16:00 23 in those trials?  
 11:16:01 24 A I don't know for a fact that I did.  
 11:16:08 25 Q Is there anything in your CV that might refresh

Page 48

PAUL VOLBERDING, M.D.

08/19/07

11:39:13 1 MS. RHYU: Objection. Vague as to time, vague  
 11:39:16 2 as to "therapy."  
 11:39:19 3 THE WITNESS: Patients can receive medications  
 11:39:23 4 through conventional prescriptions or through  
 11:39:27 5 participating in clinical investigations.  
 11:39:33 6 BY MR. CANNON:  
 11:39:34 7 Q So in 1991 when this article was published, is  
 11:39:41 8 it true that the only way for an HIV-infected patient to  
 11:39:45 9 obtain an antiretroviral therapy other than zidovudine  
 11:39:52 10 was to be enrolled in a clinical trial?  
 11:39:55 11 A When this article was published, which was,  
 11:40:00 12 again, in January, it looks to be, 1991, zidovudine was  
 11:40:05 13 the only prescription antiretroviral available, yes.  
 11:40:12 14 Q In 1991, do you know what percentage of  
 11:40:16 15 HIV-infected patients were enrolled in clinical trials?  
 11:40:22 16 MS. RHYU: Objection. Calls for speculation.  
 11:40:32 17 THE WITNESS: I don't have any knowledge of how  
 11:40:34 18 many patients were involved in clinical trials in 1991.  
 11:40:44 19 BY MR. CANNON:  
 11:40:44 20 Q Is it fair to say that in 1991 the majority of  
 11:40:49 21 patients who suffered from HIV infection were not  
 11:40:52 22 receiving therapy -- antiretroviral therapy, other than  
 11:40:57 23 zidovudine?  
 11:40:58 24 MS. RHYU: Objection. Calls for speculation,  
 11:41:00 25 lacks foundation.

Page 53

11:42:20 1 several hundred physicians involved in clinical trials  
 11:42:24 2 in 1990 and 1991.  
 11:42:27 3 Q Would your answers change if the time frame  
 11:42:35 4 moved up to 1992, to the previous set of questions and  
 11:42:39 5 answers?  
 11:42:39 6 MS. RHYU: Objection. Compound, vague.  
 11:42:42 7 THE WITNESS: During 1990 to 1992, there were  
 11:42:52 8 large clinical trials in progress across the country,  
 11:42:58 9 but I don't know how many patients were treated in any  
 11:43:01 10 one of those years.  
 11:43:08 11 BY MR. CANNON:  
 11:43:11 12 Q Is it fair to say that as of May 1992, the  
 11:43:14 13 majority of HIV-infected patients were not receiving  
 11:43:19 14 antiretroviral therapy other than zidovudine?  
 11:43:25 15 MS. RHYU: Objection. Vague as to  
 11:43:28 16 "antiretroviral therapy" and calls for speculation.  
 11:43:39 17 THE WITNESS: In 1992, I don't know the  
 11:43:43 18 fraction of patients receiving antiretroviral through  
 11:43:47 19 clinical trials versus through common -- through  
 11:43:49 20 available prescriptions, but there were many patients on  
 11:43:55 21 clinical trials at the time.  
 11:43:58 22 BY MR. CANNON:  
 11:43:58 23 Q But the majority of the patients were not  
 11:44:01 24 involved in clinical trials; right?  
 11:44:02 25 A I actually don't know that.

Page 55

11:41:03 1 THE WITNESS: Very few patients were being  
 11:41:06 2 treated in 1991 with HIV infection.  
 11:41:10 3 BY MR. CANNON:  
 11:41:10 4 Q With HIV infection or for HIV infection?  
 11:41:17 5 A Both, probably.  
 11:41:19 6 Q When you say "very few patients," you mean very  
 11:41:22 7 few patients were being treated with drugs other than  
 11:41:25 8 zidovudine?  
 11:41:26 9 A Zidovudine was the most used drug for the  
 11:41:31 10 treatment of HIV infection in early 1991.  
 11:41:36 11 Q So other than that drug, very few patients were  
 11:41:42 12 being treated with other drugs?  
 11:41:48 13 MS. RHYU: Objection. Calls for speculation,  
 11:41:49 14 lacks foundation, misstates prior testimony.  
 11:41:53 15 THE WITNESS: I think, as I said, the patients  
 11:41:54 16 were participating in clinical investigation of other  
 11:41:57 17 drugs, including other nucleosides, nonnucleosides, and  
 11:42:02 18 proteases in 1990, 1991.  
 11:42:07 19 BY MR. CANNON:  
 11:42:07 20 Q Do you know how many patients were involved in  
 11:42:09 21 those trials?  
 11:42:09 22 A Not as I sit here, no.  
 11:42:11 23 Q Do you know how many treating physicians were  
 11:42:13 24 involved with those trials?  
 11:42:14 25 A I think, as I said earlier, there were probably

Page 54

11:44:34 1 MR. CANNON: Let's mark the next exhibit.  
 11:44:34 2 (Deposition Exhibit 7 marked.)  
 11:44:54 3 MR. CANNON: Marked as Exhibit 7, an essay  
 11:45:00 4 published in The Journal of Infectious Diseases in 1995,  
 11:45:08 5 and it appears to be written by Paul Volberding.  
 11:45:11 6 Q Do you recall writing this essay in The Journal  
 11:45:18 7 of Infectious Diseases around 1995?  
 11:45:18 8 A I actually don't specifically remember writing  
 11:45:24 9 this. I believe that I did.  
 11:45:38 10 Q So this is 1995, so we've moved up in that time  
 11:45:42 11 frame past May 1992 and up into 1995. And I'd like to  
 11:45:47 12 focus your attention on the first sentence here, it  
 11:45:49 13 reads, "Current therapy for human immunodeficiency virus  
 11:45:54 14 (HIV) disease includes one or more of the available  
 11:45:56 15 nucleoside analogues that inhibit reverse  
 11:46:01 16 transcriptase." Do you see that?  
 11:46:02 17 A I do.  
 11:46:03 18 MS. RHYU: Feel free to review the rest of the  
 11:46:05 19 paragraph, Dr. Volberding.  
 11:46:10 20 BY MR. CANNON:  
 11:46:10 21 Q That first sentence is an accurate statement,  
 11:46:12 22 is it not?  
 11:46:14 23 MS. RHYU: Objection. Document speaks  
 11:46:16 24 for itself.  
 11:46:16 25 THE WITNESS: It's what I said, yes.

Page 56

14 (Pages 53 to 56)



PAUL VOLBERDING, M.D.

08/19/07

12:12:15 1 is relevant to. If you can identify what opinion or  
12:12:18 2 what claim term that question is relevant to, I'd be  
12:12:22 3 happy to let the witness answer that question.

12:12:24 4 MR. CANNON: How about "therapeutically  
12:12:25 5 effective," that's a claim term. It's relates to  
12:12:28 6 therapeutically effective.

12:12:51 7 MS. RHYU: Okay, with the caveat that in the  
12:12:53 8 context of construction of therapeutically effective,  
12:12:57 9 the witness is answering the question.

12:12:58 10 Go ahead and answer the question,  
12:13:00 11 Dr. Volberding.

12:13:00 12 MR. CANNON: Well, there's no caveats. I mean,  
12:13:02 13 it's a question and an answer, so, you know, he gets to  
12:13:06 14 give his full and complete testimony. He doesn't get to  
12:13:09 15 give it subject to any, you know, limitations. Either  
12:13:12 16 it's an answer or it's not an answer, so I can't accept  
12:13:17 17 an answer with caveats. I mean, you can make objections  
12:13:20 18 and reserve rights all you want, but I need the witness  
12:13:23 19 to give a complete answer, and if you instruct him not  
12:13:25 20 to answer, okay, we'll deal with that later, but --

12:13:27 21 MS. RHYU: The witness can answer the question,  
12:13:30 22 I'm objecting as to the aspect of the answer and the  
12:13:32 23 question that go -- that goes beyond the scope of this  
12:13:36 24 deposition.

12:13:38 25 MR. CANNON: Okay.

Page 73

12:15:11 1 load test.

12:15:14 2 Q But you've ordered viral load tests -- strike  
12:15:14 3 that.

12:15:18 4 But you have ordered patients to do viral load  
12:15:21 5 tests over the years; correct?

12:15:23 6 A Yes, of course.

12:15:24 7 Q And can you tell me the reason that you have  
12:15:25 8 ordered patients to obtain viral load tests over the  
12:15:29 9 years?

12:15:30 10 MS. RHYU: Objection to the extent it's outside  
12:15:31 11 the scope.

12:15:33 12 THE WITNESS: Either in the context of clinical  
12:15:42 13 care, or in the course of clinical investigations.

12:15:47 14 BY MR. CANNON:

12:15:48 15 Q But what is the medical reason for ordering a  
12:15:50 16 viral load test for a patient infected with HIV?

12:15:54 17 MS. RHYU: Objection. Lacks foundation and  
12:15:55 18 vague, and outside the scope.

12:15:59 19 THE WITNESS: Viral load tests help to -- or  
12:16:05 20 they help to establish the stage of HIV disease.

12:16:15 21 BY MR. CANNON:

12:16:15 22 Q Do they help to establish or do they absolutely  
12:16:18 23 establish?

12:16:19 24 A They help to establish.

12:16:22 25 Q Are there other factors that bear upon the

Page 75

12:13:39 1 Could you repeat my question back and let's see  
12:13:42 2 if we can get an answer.

12:14:07 3 (Record read as follows:

12:14:07 4 "Q This is a yes-or-no question  
12:14:07 5 I'm asking. Do you know, sitting here  
12:14:07 6 today, the reason that you directed the  
12:14:07 7 first patient that you can recall to get  
12:14:09 8 a viral load testing measurement done?")

12:14:09 9 THE WITNESS: No.

12:14:14 10 MR. CANNON: Can you ask the first question I  
12:14:15 11 asked that got an instruction not to answer?

12:14:40 12 (Record read as follows:

12:14:40 13 "Q Dr. Volberding, when you first  
12:14:40 14 directed a patient to obtain a viral  
12:14:40 15 load measurement, can you tell me why  
12:14:40 16 you directed the patient to obtain a  
12:14:41 17 viral load measurement?")

12:14:41 18 MS. RHYU: Objection. Outside the scope.

12:14:42 19 THE WITNESS: I don't recall the reason that I  
12:14:44 20 ordered the first viral load testing, I don't remember  
12:14:47 21 ordering my first viral load test in a patient.

12:14:57 22 BY MR. CANNON:

12:14:57 23 Q What's the earliest time that you can remember  
12:15:00 24 ordering a viral load test?

12:15:02 25 A I don't recall when I ordered the first viral

Page 74

12:16:27 1 state of HIV disease?

12:16:29 2 MS. RHYU: Objection. Outside the scope. And  
12:16:32 3 instruct the witness not to answer unless you can  
12:16:40 4 identify what claim construction this is relevant to.

12:16:43 5 (Instruction not to answer.)

12:16:43 6 MR. CANNON: It's all relevant to  
12:16:46 7 "therapeutically effective."

12:16:49 8 MS. RHYU: Just a minute. Are you asking from  
12:17:02 9 the perspective of one of skill in the art in the '90,  
12:17:08 10 '92 time frame?

12:17:09 11 MR. CANNON: Can you repeat my question back.  
12:17:20 12 (Record read.)

12:17:23 13 MS. RHYU: Are you asking the question as it  
12:17:25 14 stands?

12:17:26 15 MR. CANNON: Just asking the question.

12:17:27 16 MS. RHYU: Vague as to time frame. And object  
12:17:32 17 as to being outside the scope.

12:17:35 18 THE WITNESS: So in the time frame of the case,  
12:17:39 19 from 1990 to 1992, a person of skill in the art would  
12:17:48 20 use a variety of factors to consider the patient's stage  
12:17:54 21 of disease, including CD4 counts and clinical symptoms  
12:17:59 22 and signs.

12:17:59 23 BY MR. CANNON:

12:17:59 24 Q How about today, same set of factors evaluated?

12:18:06 25 A Today --

Page 76

19 (Pages 73 to 76)

PAUL VOLBERDING, M.D.

08/19/07

12:18:07 1 MS. RHYU: Objection. Outside the scope, not  
 12:18:10 2 relevant to claim construction.  
 12:18:12 3 THE WITNESS: Today, those would still be  
 12:18:14 4 considered along with viral load.  
 12:18:19 5 MR. CANNON: Let's take a break to change the  
 12:18:20 6 tape.  
 12:18:21 7 THE VIDEOGRAPHER: The time is 12:18 p.m.  
 12:18:24 8 We're going off the record, and this will be the  
 12:18:26 9 completion of media number 1.  
 12:22:11 10 (Interruption in the proceedings.)  
 12:22:18 11 THE VIDEOGRAPHER: The time is 12:22. We are  
 12:22:26 12 back on the record, and this will be the beginning of  
 12:22:28 13 media number 2. Please proceed.  
 12:22:30 14 BY MR. CANNON:  
 12:22:32 15 Q So I asked some questions about Exhibit 11,  
 12:22:34 16 which is the last exhibit we marked, which is "HIV viral  
 12:22:37 17 load markers in clinical practice." You see that? And  
 12:22:43 18 I just would like to note -- I'd like you to agree with  
 12:22:45 19 me, I think it's accurate, that this article, which I've  
 12:22:49 20 provided to you as Exhibit 11 in color, you had provided  
 12:22:52 21 in the packet of articles, which we marked collectively  
 12:22:56 22 as Exhibit 2. And if you could confirm that for me by  
 12:23:02 23 looking at Exhibit 2, that's the collection of articles  
 12:23:04 24 that has the band around it, and it's the second-from-  
 12:23:10 25 the-last article, bears the labels VOLB 2325 on the

Page 77

12:24:35 1 the question.  
 12:24:36 2 BY MR. CANNON:  
 12:24:37 3 Q Isn't it true, in the treatment of HIV, testing  
 12:24:41 4 for the presence of HIV is a different test than testing  
 12:24:44 5 for viral load?  
 12:24:46 6 MS. RHYU: Objection. Vague, outside the scope  
 12:24:49 7 of this witness's testimony, lacks foundation.  
 12:25:04 8 THE WITNESS: Could you repeat the question  
 12:25:05 9 again? I'm sorry.  
 12:25:06 10 MR. CANNON: Sure.  
 12:25:06 11 Could you read it back, please.  
 12:25:27 12 (Record read.)  
 12:25:27 13 MS. RHYU: Same objections.  
 12:25:31 14 THE WITNESS: I'm not sure that I agree with  
 12:25:36 15 the premise.  
 12:25:38 16 BY MR. CANNON:  
 12:25:41 17 Q Viral load is a quantitative HIV RNA technique;  
 12:25:44 18 right?  
 12:25:45 19 MS. RHYU: Objection. Lacks foundation, vague,  
 12:25:51 20 lacks context, and outside the scope of this witness's  
 12:25:54 21 testimony.  
 12:25:55 22 THE WITNESS: Viral load testing, as we've said  
 12:26:02 23 earlier, refers to the measurement of the number of  
 12:26:06 24 copies of HIV RNA per unit of volume in the blood.  
 12:26:10 25 BY MR. CANNON:

Page 79

12:23:18 1 first page. You see that?  
 12:23:20 2 A Yes, I do.  
 12:23:21 3 Q Same article; right?  
 12:23:22 4 A Appears to be.  
 12:23:23 5 Q So this article, Exhibit 11, refers to viral  
 12:23:34 6 load, and we discussed earlier a viral load refers to  
 12:23:39 7 copy number of HIV; right?  
 12:23:41 8 A I'm sorry?  
 12:23:45 9 Q The viral load refers to copy number of HIV?  
 12:23:48 10 MS. RHYU: Objection. Vague.  
 12:23:50 11 BY MR. CANNON:  
 12:23:51 12 Q Is that accurate?  
 12:23:52 13 A Yes.  
 12:23:52 14 Q Now, you would agree, wouldn't you, that a test  
 12:23:58 15 for viral load is different from a test that determines  
 12:24:02 16 whether the virus is actually present in a sample;  
 12:24:06 17 right?  
 12:24:06 18 MS. RHYU: Objection. Vague, outside the scope  
 12:24:08 19 of this witness's testimony, lacks foundation.  
 12:24:10 20 THE WITNESS: Could you repeat the question?  
 12:24:14 21 MR. CANNON: Sure.  
 12:24:14 22 Could you read it back for me, please.  
 12:24:29 23 (Record read.)  
 12:24:31 24 MS. RHYU: Same objections.  
 12:24:33 25 THE WITNESS: I'm not really sure I understand

Page 78

12:26:11 1 Q That's quantitative; right?  
 12:26:13 2 MS. RHYU: Object -- same objections.  
 12:26:18 3 THE WITNESS: Quantitative and qualitative.  
 12:26:20 4 BY MR. CANNON:  
 12:26:21 5 Q How is it qualitative?  
 12:26:23 6 MS. RHYU: Objection. Outside the scope of  
 12:26:24 7 this witness's testimony, lacks foundation.  
 12:26:29 8 THE WITNESS: It's quantitative -- the viral  
 12:26:36 9 load testing itself is quantitative, you're measuring  
 12:26:41 10 the number of copies, that's the purpose of viral load  
 12:26:45 11 testing.  
 12:26:46 12 BY MR. CANNON:  
 12:26:47 13 Q You said it was qualitative as well.  
 12:26:50 14 A Well --  
 12:26:51 15 MS. RHYU: Objection. Misstates the testimony,  
 12:26:54 16 outside the scope. And what's the question?  
 12:27:01 17 BY MR. CANNON:  
 12:27:02 18 Q I'm asking how is a viral load test  
 12:27:04 19 qualitative?  
 12:27:05 20 A I would say quantitation of virus is not  
 12:27:09 21 qualitative, it's quantitative.  
 12:27:12 22 Q So in Exhibit 11, which is the HIV viral load  
 12:27:30 23 markers in clinical practice essay -- article, refers to  
 12:27:36 24 three commercially available assays, starting at the  
 12:27:40 25 bottom of the first column and going to the top of the

Page 80

PAUL VOLBERDING, M.D.

08/19/07

12:27:43 1 second column. You see that?  
 12:27:44 2 A This is on page 626?  
 12:27:48 3 Q 625. Bottom of the first column says, "The  
 12:27:54 4 Assays." Do you see that?  
 12:27:57 5 A Okay, yes.  
 12:28:01 6 Q And then the sentence in the paragraph  
 12:28:04 7 continues to the top of the second column. Do you see  
 12:28:07 8 that?  
 12:28:07 9 A Yes, I do.  
 12:28:08 10 Q This article refers to three commercial HIV RNA  
 12:28:18 11 assays; right?  
 12:28:19 12 A Yes, it does.  
 12:28:20 13 Q In your practice, do you recommend one type of  
 12:28:25 14 assay over another?  
 12:28:28 15 MS. RHYU: Objection. Outside the scope.  
 12:28:38 16 THE WITNESS: I'm not sure in every case which  
 12:28:40 17 assay is being used in my practice.  
 12:28:43 18 BY MR. CANNON:  
 12:28:44 19 Q So when you direct a patient to obtain a viral  
 12:28:47 20 load measurement, you don't recommend a particular type  
 12:28:50 21 of assay to be used?  
 12:28:52 22 MS. RHYU: Objection. Outside the scope.  
 12:28:54 23 THE WITNESS: Typically not.  
 12:28:55 24 BY MR. CANNON:  
 12:28:59 25 Q When you get the results, do you know the type

Page 81

12:30:21 1 get sent?  
 12:30:23 2 MS. RHYU: Objection. Outside the scope.  
 12:30:24 3 THE WITNESS: Of course.  
 12:30:26 4 BY MR. CANNON:  
 12:30:29 5 Q When you get the results back, does the lab  
 12:30:31 6 make recommendations about the therapy for a particular  
 12:30:33 7 patient?  
 12:30:34 8 MS. RHYU: Objection. Outside the scope. Can  
 12:30:45 9 you identify what claim construction term your question  
 12:30:48 10 relates to, Brian?  
 12:30:52 11 MR. CANNON: All of my questions today relate  
 12:30:53 12 to "therapeutically effective" and the remainder of the  
 12:30:56 13 claim terms at issue.  
 12:31:06 14 MS. RHYU: I don't see how that question that  
 12:31:08 15 you posed regarding lab recommendations today relate to  
 12:31:16 16 construction of the claim term "therapeutically  
 12:31:19 17 effective." Can you make a connection there?  
 12:31:22 18 MR. CANNON: Well, then you can instruct him  
 12:31:24 19 not to answer. I don't need to lay out for you where  
 12:31:26 20 I'm going or what my strategy is.  
 12:31:27 21 MS. RHYU: Okay. Then I instruct the witness  
 12:31:29 22 not to answer.  
 12:31:29 23 (Instruction not to answer.)  
 12:31:29 24 MR. CANNON: Could you repeat my question back  
 12:31:31 25 so we get the instruction clearly?

Page 83

12:29:02 1 of assay that was used to generate the results?  
 12:29:04 2 MS. RHYU: Objection. Outside the scope. I'm  
 12:29:07 3 not going to let this go very much further than this,  
 12:29:10 4 Brian.  
 12:29:11 5 THE WITNESS: It's often -- if it's in the  
 12:29:17 6 course of a clinical trial, I know which assay is being  
 12:29:21 7 used in the context of clinical trial, and typically in  
 12:29:24 8 a clinical laboratory, the type of assay is mentioned in  
 12:29:30 9 the results.  
 12:29:32 10 BY MR. CANNON:  
 12:29:33 11 Q How about not in a clinical trial but just  
 12:29:35 12 treating, you know, an HIV-infected patient?  
 12:29:39 13 A That's what I just said.  
 12:29:41 14 MS. RHYU: Same objection.  
 12:29:41 15 BY MR. CANNON:  
 12:29:42 16 Q So you would know, when you got the results,  
 12:29:43 17 which assay got used?  
 12:29:45 18 A Typically.  
 12:29:46 19 Q How long does it take for you to get the  
 12:29:54 20 results when you order a viral load test to be done?  
 12:30:01 21 MS. RHYU: Objection. Outside the scope.  
 12:30:01 22 THE WITNESS: Viral load testing results are  
 12:30:12 23 returned in a variable length of time, days to weeks.  
 12:30:16 24 BY MR. CANNON:  
 12:30:19 25 Q Does it depend on the lab to which the results

Page 82

12:31:46 1 (Record read.)  
 12:31:48 2 MS. RHYU: I instruct the witness not to answer  
 12:31:49 3 because it's outside the scope of claim construction  
 12:31:53 4 testimony.  
 12:31:55 5 BY MR. CANNON:  
 12:31:56 6 Q Dr. Volberding, when you get the results back  
 12:31:58 7 from the lab, does the manufacturer of the test kit make  
 12:32:02 8 recommendations about a patient's therapy?  
 12:32:05 9 MS. RHYU: Same instruction.  
 12:32:07 10 (Instruction not to answer.)  
 12:32:08 11 BY MR. CANNON:  
 12:32:08 12 Q When you get the results back from the lab,  
 12:32:10 13 Dr. Volberding, does the manufacturer of the test kit  
 12:32:13 14 make a determination about the effectiveness of the  
 12:32:16 15 therapy for the particular patient?  
 12:32:18 16 MS. RHYU: Same objection.  
 12:32:21 17 BY MR. CANNON:  
 12:32:21 18 Q The treating physician makes a decision --  
 12:32:23 19 MS. RHYU: And instruction, sorry.  
 12:32:24 20 (Instruction not to answer.)  
 12:32:25 21 BY MR. CANNON:  
 12:32:27 22 Q And Dr. Volberding, do you follow your  
 12:32:29 23 counsel's instructions with respect to answering the  
 12:32:32 24 last few questions?  
 12:32:33 25 A Yes, I do.

Page 84

21 (Pages 81 to 84)



PAUL VOLBERDING, M.D.

08/19/07

12:32:34 1 Q Dr. Volberding, it's true, isn't it, that the  
 12:32:40 2 treating physician makes the decision about the  
 12:32:41 3 effectiveness of therapy; correct?  
 12:32:48 4 A The effectiveness of therapy is a very broad  
 12:32:58 5 term, and is determined with input from a number of  
 12:33:03 6 sources, other people on a team. Physicians are  
 12:33:07 7 certainly involved and usually centrally involved in  
 12:33:10 8 deciding whether treatment is beneficial or not.  
 12:33:14 9 Q Who makes the ultimate decision?  
 12:33:17 10 MS. RHYU: Objection. Lacks foundation.  
 12:33:19 11 THE WITNESS: Again, the definition of  
 12:33:27 12 "treatment benefit" is a very broad one. And, in fact,  
 12:33:33 13 many people on the team can have key roles in that  
 12:33:37 14 assessment, and certainly including the physician or  
 12:33:40 15 nurse practitioner, because in some cases, physicians  
 12:33:43 16 aren't directing the care of the patient. But the  
 12:33:47 17 provider, the physician, is centrally involved in  
 12:33:53 18 participating in that assessment.  
 12:33:56 19 BY MR. CANNON:  
 12:33:56 20 Q So is it your testimony that no one person  
 12:33:58 21 makes a conclusion about the effectiveness of therapy  
 12:34:01 22 for a particular patient?  
 12:34:02 23 MS. RHYU: Objection. Misstates prior  
 12:34:05 24 testimony.  
 12:34:06 25 THE WITNESS: I think the number of people make

Page 85

12:35:19 1 THE WITNESS: I think, as I've said, the  
 12:35:22 2 physician has a central role in that determination, but  
 12:35:29 3 in fact, the information comes from a number of sources,  
 12:35:35 4 and many times the key information comes from someone  
 12:35:37 5 other than the physician.  
 12:35:38 6 BY MR. CANNON:  
 12:35:38 7 Q I understand that information may come from a  
 12:35:41 8 number of sources. I'm trying to pin down to see if  
 12:35:44 9 there is an answer for the question as to who makes the  
 12:35:47 10 ultimate conclusion, if anyone, about the effectiveness  
 12:35:50 11 of therapy for a particular patient.  
 12:35:53 12 A Well, and in terms of accepting responsibility  
 12:35:57 13 for the decision, I think many of the people on the team  
 12:36:00 14 that I just mentioned would share in that  
 12:36:03 15 responsibility. Certainly, again, I'm not saying the  
 12:36:06 16 physician doesn't have an important role in that.  
 12:36:10 17 Q But is it your testimony that the physician is  
 12:36:13 18 not the only person that makes the conclusion about the  
 12:36:16 19 effectiveness of therapy?  
 12:36:18 20 A That's correct.  
 12:36:18 21 Q Does the lab that performed the assay make a  
 12:36:30 22 conclusion about the effectiveness of therapy?  
 12:36:33 23 MS. RHYU: You're asking about that today?  
 12:36:35 24 MR. CANNON: Today.  
 12:36:35 25 MS. RHYU: I instruct the witness not to answer

Page 87

12:34:09 1 the conclusion about therapy effectiveness. As I said,  
 12:34:15 2 the provider, the physician especially, is centrally  
 12:34:18 3 involved in that.  
 12:34:20 4 BY MR. CANNON:  
 12:34:21 5 Q Can you tell me who are the people that make  
 12:34:24 6 the conclusion about the effectiveness of therapy?  
 12:34:27 7 MS. RHYU: Objection. Lacks foundation.  
 12:34:32 8 THE WITNESS: And may I ask you a question?  
 12:34:36 9 BY MR. CANNON:  
 12:34:37 10 Q Sure.  
 12:34:37 11 A You're asking this in the context of my  
 12:34:40 12 practice today?  
 12:34:41 13 Q I'm asking today, yeah.  
 12:34:42 14 A The people that --  
 12:34:45 15 MS. RHYU: And again, objection. Outside the  
 12:34:47 16 scope.  
 12:34:51 17 THE WITNESS: The input into treatment benefit  
 12:34:57 18 would come from pharmacists, nurses, social workers,  
 12:35:05 19 family members, the patient, him or herself, and the  
 12:35:08 20 physician.  
 12:35:10 21 BY MR. CANNON:  
 12:35:10 22 Q So no one person makes the conclusion about the  
 12:35:14 23 effectiveness of therapy for a particular patient?  
 12:35:17 24 MS. RHYU: Objection. Misstates prior  
 12:35:18 25 testimony.

Page 86

12:36:38 1 as being outside the scope of this deposition.  
 12:36:39 2 (Instruction not to answer.)  
 12:36:39 3 BY MR. CANNON:  
 12:36:40 4 Q Do you follow counsel's instructions?  
 12:36:42 5 A Yes, I do.  
 12:36:43 6 Q Does the manufacturer of the test kit make a  
 12:36:47 7 conclusion about the effectiveness of therapy for a  
 12:36:51 8 particular patient?  
 12:36:52 9 MS. RHYU: Same instruction.  
 12:36:53 10 (Instruction not to answer.)  
 12:36:53 11 BY MR. CANNON:  
 12:36:54 12 Q Do you follow counsel's instruction?  
 12:36:55 13 A I do.  
 12:37:07 14 MR. CANNON: Now would be a good time to stop  
 12:37:09 15 for a break?  
 12:37:09 16 MS. RHYU: I'm not sure. Yes, why don't we  
 12:37:14 17 stop. I hear the elevator.  
 12:37:17 18 THE VIDEOGRAPHER: The time is 12:37. We're  
 12:37:18 19 going off the record.  
 13:24:03 20 (Lunch recess.)  
 13:26:59 21 THE VIDEOGRAPHER: Good afternoon. The time is  
 13:27:01 22 1:27. We are back on the record.  
 13:27:05 23 BY MR. CANNON:  
 13:27:05 24 Q Dr. Volberding, before the break we were  
 13:27:08 25 looking at Exhibit 11, which was an article from Nature

Page 88



PAUL VOLBERDING, M.D.

08/19/07

<p>14:54:46 1 A That's my understanding.  14:54:49 2 Q Can you tell me what antiretroviral agents were  14:55:01 3 known to those of skill in the art as of May 1992?  14:55:04 4 A The person skilled in the art in May of 1992  14:55:13 5 would have, I think, been broadly aware of very active  14:55:25 6 development of antiviral agents, a person skilled in the  14:55:30 7 art would have certainly been aware of a number of  14:55:36 8 nucleosides, nonnucleosides and protease inhibitors by  14:55:42 9 May of 1992.  14:55:43 10 Q Would they have been aware of them by  14:55:47 11 identification or would they have been aware that  14:55:49 12 they -- that those compounds that you just identified  14:55:52 13 have clinical value in treating patients?  14:55:54 14 A They would have been aware of them either  14:56:01 15 because of use, in the case of the several that were  14:56:04 16 available by prescription, or by their preclinical and  14:56:11 17 clinical development which varied among the drugs at the  14:56:15 18 time, and by the level of involvement of the person  14:56:22 19 skilled in the art in clinical investigation, which  14:56:24 20 again, is part of my definition of a person skilled in  14:56:26 21 the art.  14:56:27 22 Q Is it -- are the results of clinical trials  14:56:35 23 publicly known to those of skill in the art before the  14:56:39 24 data is presented in papers or conferences?  14:56:47 25 A The data is typically made available to an</p> <p style="text-align: right;">Page 137</p>	<p>14:59:26 1 mentions a Dr. John G. Bartlett. Do you see that?  14:59:30 2 A I do.  14:59:30 3 Q Do you know Dr. Bartlett?  14:59:32 4 A Yes, I do.  14:59:32 5 Q Can you tell me who he is?  14:59:34 6 A He's a physician at Johns Hopkins University.  14:59:39 7 Q Is he a well-respected physician?  14:59:40 8 A Yes, he is.  14:59:41 9 Q Do you have a professional relationship with  14:59:43 10 him?  14:59:43 11 A Yes, I do.  14:59:44 12 Q Page 3 of the -- of this document references  15:00:00 13 someone called Jeffrey D. Lifson. Do you see that?  15:00:04 14 A I do see that.  15:00:05 15 Q Do you know who Dr. Lifson is?  15:00:07 16 A Yes, I do.  15:00:08 17 Q Can you tell me who he is?  15:00:09 18 A I don't know Jeff well anymore, so I would rely  15:00:18 19 on the statement as to his current position, but he's a  15:00:22 20 person who's been involved in HIV research in the past.  15:00:25 21 Q Is he a respected scientist?  15:00:28 22 A Yes, I believe so.  15:00:29 23 Q Before today, did you have the opportunity to  15:00:37 24 read the section beginning in the middle of page 3 and  15:00:42 25 over to page 4 under Jeffrey D. Lifson's name, which</p> <p style="text-align: right;">Page 139</p>
<p>14:56:53 1 investigator in a specific clinical trial as that trial  14:56:58 2 is being analyzed, which can happen slightly before  14:57:04 3 public presentation, but in HIV, the pace of development  14:57:10 4 was such that most developments were available publicly  14:57:17 5 in the form of scientific presentations or publications.  14:57:28 6 Q You will agree that HAART therapies were not  14:57:31 7 available to those of skill in the art as of May 1992?  14:57:36 8 MS. RHYU: Objection. Compound and vague.  14:57:39 9 THE WITNESS: I think we addressed that  14:57:41 10 earlier, and said that the availability of the elements  14:57:50 11 of that acronym, especially the nonnucleosides and  14:57:55 12 proteases, were entering clinical development in 1990  14:58:01 13 through 1992, and may have, in fact, been combined in  14:58:06 14 ways that would be called HAART, but the term hadn't  14:58:13 15 really been coined yet.  14:58:45 16 (Deposition Exhibit 17 marked.)  14:58:45 17 MR. CANNON: Marking, as Exhibit 17, a document  14:58:52 18 entitled "Joint Claim Construction and Prehearing  14:58:54 19 Statement Under Patent Local Rule 4-3."  14:58:58 20 Q Have you seen this document before,  14:59:04 21 Dr. Volberding?  14:59:05 22 A Yes. I don't recall whether I've seen it in  14:59:07 23 exactly this format or not, but yes, I've seen this  14:59:13 24 document before.  14:59:14 25 Q Let's take a look at Exhibit G. Exhibit G</p> <p style="text-align: right;">Page 138</p>	<p>15:00:46 1 purports to show proposed testimony and opinions from  15:00:50 2 Dr. Lifson?  15:00:51 3 A Yes, I read this.  15:00:52 4 Q Do you have any opinions about the statements  15:00:57 5 or proposed testimony set forth for Dr. Lifson here?  15:01:00 6 MS. RHYU: Objection. Compound.  15:01:02 7 THE WITNESS: If you could give me just a  15:01:04 8 minute to --  15:01:04 9 BY MR. CANNON:  15:01:04 10 Q Sure.  15:01:05 11 A -- refresh my memory of this document.  15:01:07 12 Q Sure. Take your time.  15:01:37 13 A Okay, your question again?  15:01:41 14 Q Do you disagree with any of the proposed  15:01:44 15 testimony of Dr. Lifson?  15:01:45 16 MS. RHYU: Objection. Outside the scope.  15:01:47 17 THE WITNESS: It's not --  15:01:49 18 MS. RHYU: And compound. If you want to ask  15:01:51 19 him about specific statements one at a time, go for it.  15:01:58 20 THE WITNESS: In general, it's not an area that  15:02:00 21 I would be expected to address in any real detail.  15:02:07 22 BY MR. CANNON:  15:02:14 23 Q Following up counsel's objection, to make sure  15:02:16 24 that -- make sure that we're on the same page, the  15:02:20 25 bottom of page 3 of this document states, "He" -- and</p> <p style="text-align: right;">Page 140</p>

35 (Pages 137 to 140)

PAUL VOLBERDING, M.D.

08/19/07

15:39:03 1	scope, and misleading.	1	
15:39:06 2	THE WITNESS: And I'm really sorry, maybe it's	2	
15:39:10 3	the time of day, but could I hear the question one more	3	
15:39:13 4	time?	4	
15:39:13 5	MR. CANNON: Of course. Of course. As many	5	
15:39:15 6	times as you need.	6	
15:39:16 7	Please read it back.	7	
15:39:34 8	(Record read.)	8	
15:39:34 9	MS. RHYU: And I have to object that this is	9	
15:39:35 10	very misleading. If you want to aim him toward any	10	I, PAUL VOLBERDING, M.D., do hereby declare
15:39:40 11	results in there that relates to monitoring of	11	under penalty of perjury that I have read the foregoing
15:39:45 12	antiretroviral therapy, please do that, or give him the	12	transcript; that I have made any corrections as appear
15:39:47 13	opportunity to read the entire article, but this is	13	noted, in ink, initialed by me, or attached hereto; that
15:39:50 14	really unfair to throw that article in front of the	14	my testimony as contained herein, as corrected,
15:39:53 15	witness and ask him to answer that question when he	15	is true and correct.
15:39:55 16	hasn't considered it prior to this deposition.	16	EXECUTED this ____ day of _____,
15:40:00 17	THE WITNESS: So the article in Exhibit 13	17	20 ____, at _____,
15:40:06 18	summarizes the results of some of the development of	18	(City) (State)
15:40:11 19	viral load quantitation and patients with HIV infection.	19	
15:40:16 20	BY MR. CANNON:	20	
15:40:16 21	Q Right. And you considered this article	21	
15:40:22 22	important when you read it back in 1991; correct?	22	
15:40:25 23	A I think this is an important article.	23	PAUL VOLBERDING, M.D.
15:40:30 24	MR. CANNON: No further questions.	24	
15:40:34 25	MS. RHYU: Thank you.	25	
Page 157		Page 159	
15:40:35 1	MR. CANNON: Thanks very much for your time, I	1	I, the undersigned, a Certified Shorthand
15:40:38 2	appreciate it.	2	Reporter of the State of California, do hereby certify:
15:40:38 3	THE WITNESS: Oh, yeah.	3	That the foregoing proceedings were taken
15:40:40 4	THE VIDEOGRAPHER: This concludes today's	4	before me at the time and place herein set forth; that
15:40:42 5	deposition of Dr. Paul Volberding. The number of media	5	any witnesses in the foregoing proceedings, prior to
15:40:50 6	used was three. We're going off the record at 3:40 p.m.	6	testifying, were duly sworn; that a record of the
7	//	7	proceedings was made by me using machine shorthand
8	//	8	which was thereafter transcribed under my direction;
9		9	that the foregoing transcript is a true record of the
10		10	testimony given.
11		11	Further, that if the foregoing pertains to
12		12	the original transcript of a deposition in a Federal
13		13	Case, before completion of the proceedings, review of
14		14	the transcript [ X ] was [ ] was not requested.
15		15	I further certify I am neither financially
16		16	interested in the action nor a relative or employee of
17		17	any attorney or party to this action.
18		18	IN WITNESS WHEREOF, I have this date
19		19	subscribed my name.
20		20	
21		21	DATED: _____
22		22	
23		23	
24		24	
25		25	GINA GLANTZ CSR No. 9795
Page 158		Page 160	

40 (Pages 157 to 160)