

APPENDIX A

Part 3 of 4

Summary of Objections in the 3/09/07 Deposition of Thomas Strickland

	recombinant EPO on any gel submitted in your declaration to the Patent Office; right?	
233 201:7-13	Not only western, there's no gel of -- stained with anything -- correct? -- for EPO containing cell-conditioned media, unpurified?	DR. LOEB: Objection. Outside the scope of the notice and the designation
234 202:19-203:1	Now, are there any data in the 178 application that support that statement?	DR. LOEB: I object as outside of the scope of the 30(b)(6) designation. If you want to look and see if you can find that. I think it also calls for expert testimony.
235 203:17-23	And the declaration that we were talking about, which is Strickland Exhibit 3, that was filed at the Patent Office to support patentability of the Lin patents; right?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice.
236 204:2-8	And the declaration was to convince the Patent Office that the carbohydrate content of EPO produced by the Lin claims was different than EPO isolated from human urine; right?	DR. LOEB: Objection. Outside of the scope of the designation. And calls for speculation.
237 205:25-206:9	Are there any data presented in the Lin patent application, 113,178, that support the statement that there are novel glycoproteins having an average carbohydrate composition which differs from that of naturally occurring human EPO?	DR. LOEB: Objection. Outside the designation of the 30(b)(6) and calls for speculation. Calls for expert testimony
238 207:5-12	Now, Amgen has data that shows by western blot SDS PAGE, that COS-cell-produced EPO runs identically to human urinary EPO; correct?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and to the extent you know, you can answer it, Dr. Strickland.
239 207:15-24	Did you look for any data on SDS PAGE gels comparing recombinant EPO and human urinary EPO, in preparation for the deposition?	DR. LOEB: Let's be clear here for a second. In preparation for your 30(b)(6) deposition today. If you looked at them for any other than that, then I would instruct you not to answer.

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240	208:4-13	Does your declaration tell the Patent Office that recombinant human EPO produced in COS-1 cells that's a molecular weight of 34,000 daltons and migrates identically to human urinary EPO standard suggesting that both the recombinant and native EPO are glycosylated to the same extent?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) designation.
241	208:19-209:1	But the patent has a statement about COS-cell EPO being different than human urinary EPO; right?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice. Is there a particular statement that you're referring to, Counselor?
242	209:10-15	That's talking about an SDS PAGE gel; right?	A That's correct. DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice.
243	209:17-25	And the specification, you're saying that the COS-cell-produced EPO runs differently on an SDS PAGE gel than human urinary EPO?	DR. LOEB: Objection. Outside the scope -- MR. JAGOE: Isolated EPO -- DR. LOEB: You want to start over, that's fine. Sorry about that.
244	210:1-8	MR. JAGOE: The Lin patent specification says that COS-cell-produced EPO runs differently on SDS PAGE than EPO isolated from human urine runs on SDS PAGE; correct?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) notice. Calls for expert testimony. And the document speaks for itself.
245	210:12-19	So what does the patent specification tell people about the difference between COS-cell-produced EPO and EPO isolated from human urine?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) designation. The document speaks for itself. Calls for expert testimony.
246	211:10-16	I don't see how that's responsive to my question, so I'm going to ask again. What does the patent tell you about the EPO produced in COS cells compared to EPO isolated from human urine when analyzed on an SDS PAGE gel?	DR. LOEB: Objection.
247	211:18-23	Are they the same or are they	DR. LOEB: Objection.

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		different?	Outside the scope of the 30(b)(6) notice. Calls for expert testimony. The document speaks for itself.
248	212:4-13	So what does -- so does the patent specification tell -- teach anything about the differences or similarities of COS-cell-produced EPO, as compared to human urinary EPO?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice, like the entire last 45 minutes. And calls for expert testimony. And the document speaks for itself.
249	212:20-24	So that means they would run differently on an SDS PAGE gel, right?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) notice. Calls for expert testimony.
250	213:6-13	And Amgen had information, at the time you filed your declaration, that Cos-cell-produced EPO migrates identically to human urinary EPO; right?	DR. LOEB: Objection. Outside of the scope of the designation. Calls for expert testimony. And calls for speculation.
251	213:18-23	And your patent -- your declaration doesn't give any information about COS-cell-produced EPO; right?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) notice.
252	214:13-21	And nothing could be inferred about recombinant Cos-cell-produced EPO from the experiments on recombinant CHO-cell-produced EPO that are in your declaration; right?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) notice. Calls for expert testimony. And I think it's really about time for a break, Counselor, if you don't mind
253	215:4-11	One cannot infer anything about the structure of Cos-cell-produced EPO from the data on CHO-cell-produced EPO that you submitted in your declaration to the Patent Office; is that correct?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) designation. Calls for expert testimony.
254	215:17-23	And you know that variations in cell-culture conditions or in the selection which occurs during purification can result in shifts in glycoform populations; right?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) designation and calls for expert testimony.
255	216:2-11	And your patent -- your declaration to the Patent Office does not explain that variations in cell-culture conditions or in the selection which occurs during purification, can result in shifts in glycoform populations;	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) notice, and -- it's just outside of the 30(b)(6) notice.

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256	216:15-20	right? And the data in the declaration is on one or two specific cell-culture conditions purified by a very specific method; right?	DR. LOEB: Objection. Vague and ambiguous as to "very specific method."
257	217:2-6	And that was GMP material, which is highly controlled; right?	DR. LOEB: Objection. Vague and ambiguous as to "highly controlled."
258	219:24-220:2	It's getting close to the urinary EPO, though; correct?	DR. LOEB: Objection. Vague and ambiguous
259	222:12-16	And do you have any doubt that it happened around the middle of November of 1984?	DR. LOEB: Objection. Mischaracterizes the witness's testimony.
260	222:20-25	This document, you believe, is dated September -- November 16th, 1984; right?	A Yes. DR. LOEB: Objection. The document speaks for itself. You haven't asked him --
261	223:6-12	And did you understand that this document reflects things that were happening at Amgen at about that time?	DR. LOEB: Objection. Calls for speculation, and he has no way of authenticating whether this is even an actual memo from Dan Vapnek.
262	223:17-23	What I'm asking you is after reading this document, if you understand it to reflect things that were taking place at Amgen in or around November of 1984?	DR. LOEB: Objection. Calls for speculation. And assumes facts that are not in evidence
263	224:13-19	Does that refresh your recollection that Jeff Browne was heading the group that was going to pursue bringing mammalian-cell-produced EPO into the clinic, and not Dr. Lin?	DR. LOEB: Objection. Compound and vague and ambiguous.
264	225:20-24	And is that consistent with your recollection about the status of the EPO project in November of 1984?	DR. LOEB: Objection. Vague and ambiguous.
265	226:6-13	Is Dr. Vapnek's statement in this document about formidable obstacles to overcome, consistent with your recollection of the EPO project team status as of November of 1984?	DR. LOEB: Objection. Assumes facts not in evidence. And vague and ambiguous.

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266	226:18-21	Do you have any reason to doubt what he's saying?	DR. LOEB: Objection. Calls for speculation.
267	227:22-25	And it indicates that Dr. Lin did not attend the meeting; right?	DR. LOEB: Objection. The document speaks for itself
268	228:12-15	And did you understand that to mean that Dr. Lin didn't attend the meeting?	DR. LOEB: Objection. Calls for speculation.
269	228:19-22	If this document is accurate, then Dr. Lin didn't attend the meeting; right?	DR. LOEB: Objection. The document speaks for itself.
270	228:25-229:11	And this would be a meeting only about two weeks after the November 16th announcement by Dr. Vapnek that the EPO product team was being split into two smaller groups; right?	DR. LOEB: Objection. The witness has never said he's got any personal knowledge about any of this stuff. I don't know why you don't establish a foundation for these documents before you ask him questions about it. Otherwise, he's just reading.
271	229:20-25	And do you doubt that Dr. Lin was not part of the MC EPO product team as of December 5th, 1984?	DR. LOEB: Objection. Lacks foundation. Calls for speculation.
272	230:11-20	Well, my question is a little bit different. So let's look at page 53470. There are certain people in the distribution list; correct? Cohen, Egrle, Fenno, Lai, Smalling, Strickland, Todge-ree [phonetic]; right? A Ta-jeer-y [phonetic]. Q Tajiri?	DR. LOEB: Objection. The document speaks for itself.
273	231:3-8	So Dr. Lai is on the distribution list, but according to this, he didn't attend the meeting; correct?	DR. LOEB: Objection. The document speaks for itself. No foundation.
274	231:13-19	And does the distribution list on Strickland 9 correspond with the members who are being identified as being part of the MCEC group in Dr. Vapnek's 1984 memo?	DR. LOEB: Objection. Lacks foundation. And the documents both speak for themselves.
275	234:1-6	What was the intended purpose of the invention described in this patent?	DR. LOEB: Are you asking him what it says in the patent? Objection. Vague and ambiguous.

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276	234:11-15	It's for a purification process that would allow you to produce biologically active material from mammalian cells grown in culture?	DR. LOEB: Objection. Calls for a legal conclusion.
277	235:17-23	Doesn't that indicate that the problem to be solved by your invention is to isolate biologically active erythropoietin from mammalian cells grown in culture?	DR. LOEB: Objection. Calls for a legal conclusion. Calls for expert testimony.
278	236:6-10	Was that one of the purposes of your patent?	DR. LOEB: Objection. Calls for a legal conclusion. Calls for expert testimony.
279	236:14-21	You put something in your last answer about "just." And I never asked you "just," but I'm asking you: Does that paragraph that I read into the record describe the problem that your invention was intended to solve?	DR. LOEB: Objection. Calls for a legal conclusion. Calls for expert testimony.
280	237:2-6	Are there any other problems that the procedures were expected to solve?	DR. LOEB: Objection. Calls for a legal conclusion. Calls for expert testimony.
281	237:10-14	Do you recall when you recognized that you had a procedure that would solve this problem?	DR. LOEB: Objection. Lacks foundation.
282	237:24-238:5	Well, to know that you were solving this problem, would you have had to test the material produced by the method in any type of way?	DR. LOEB: Objection. Calls for speculation and expert testimony. It's an incomplete hypothetical.
283	238:11-14	And how would you show that the various contaminants had been removed?	DR. LOEB: Objection. Calls for expert testimony.
284	239:13-19	Isn't it true, Doctor, that gel electrophoresis in the presence of SDS are not reliable because the method is confounded by animalus behavior of glycoproteins in SDS polyacrylamide gel electrophoresis?	DR. LOEB: Objection. Calls for expert testimony.
285	240:6-10	And what -- why do glycoproteins confound the results from SDS polyacrylamide gel electrophoresis?	DR. LOEB: Objection. Calls for expert testimony.
286	242:11-17	In the declaration, did you explain to the Patent Office that glycoproteins can	DR. LOEB: Objection. Outside the scope of the 30(b)(6)

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		confound the results of SDS PAGE gel electrophoresis analysis?	topic, as defined by Roche.
287	242:23-243:8	But the Lin patent specification does make a point about urinary EPO and recombinant EPO having different molecular weights; right?	DR. LOEB: Outside the scope of the 30(b)(6) topic as defined by Roche. And the document speaks for itself.
		--	
		DR. LOEB: Objection.	
		BY MR. JAGOE:	
		Q -- based on SDS gel page electrophoresis?	
288	243:20-244:3	And that is inappropriate extrapolation, based on your understanding of how glycoproteins can confound SDS PAGE analyses?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic. Calls for expert testimony and mischaracterizes the witness's previous testimony.
289	244:13-22	Didn't you publish a paper comparing recombinantly produced EPO from Chinese hamster ovary cells to urinary EPO and make that statement about why SDS is not reliable?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic. And if you're going to ask him about a paper, the fair thing to do would be to show it to him.
290	245:8-19	In the declaration you filed to the Patent Office, the 1988 declaration that's Strickland Exhibit 3, did you explain to the patent examiner that the protein produced in Chinese hamster ovary cells showed a confirmation apparently identical with the natural product isolated from human urine when examined by circular dichroism, UV absorbants and fluorescence spectroscopy?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) topic.
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292	245:25-246:5	And why didn't Amgen discuss those techniques in the declaration that you submitted to the Patent Office?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic and calls for speculation.
293	246:11-17	And you were trying to imply that that difference was somehow important to the	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic.

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		patentability of Dr. Lin's invention?	topic. And mischaracterizes the witness's previous testimony.
294	246:21-247:10	You said that you didn't discuss the techniques of circular dichroism, UV absorbants and fluorescence spectroscopy because the subject of the declaration was to the differences in carbohydrates between urinary and recombinant EPO. And I asked you was -- in the declaration, were you trying to tell the Patent Office that the difference in carbohydrates between urinary and recombinant EPO was important to the patentability of Dr. Lin's invention?	DR. LOEB: Objection. Outside of the 30(b)(6) notice. Mischaracterizes the witness's testimony.
295	247:15-20	But at the same time, you knew there were other techniques that showed they were the same?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic. And vague and ambiguous.
296	247:25-248:3	And those were not included in the declaration?	DR. LOEB: Objection. Outside of the scope of the topic.
297	248:8-248:15	Were there -- was there any disclosure in the declaration of an assay that showed how CHO-cell- produced recombinant EPO was the same as EPO isolated from human urine?	DR. LOEB: Outside of the scope of the 30(b)(6) topic. Sounds like you need to look at the declaration to be able to answer that question.
298	248:20-25	And that would show that the compounds have the same amino acid sequence as each other?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) topic and also calls for expert testimony.
299	249:8-14	Is the CHO-cell-produced recombinant EPO glycosylated on three specific asparagine amino acids?	DR. LOEB: Objection. Outside the deposition -- 30(b)(6) deposition topic and calls for expert testimony.
300			
301	250:23-251:3	Is that a true statement; that EPO produced in CHO cells is glycosylated on three specific asparagine residues?	DR. LOEB: Objection. Outside of the 30(b)(6) notice and calls for expert testimony.
302	251:6-11	Is it glycosylated on any other amino acids?	A Yes. DR. LOEB: Objection.

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			Outside of the scope of the 30(b)(6) notice.
303	251:13-17	What other amino acid is CHO-cell-produced human EPO glycosylated on?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice.
304	251:20-252:2	Q A specific serine? A Yes. Q What is the number? A 126.	DR. LOEB: Objection. Outside of the scope. THE WITNESS: Sorry. DR. LOEB: Pause a little longer.
305	252:4-8	Q Are the asparagines, asparagines 24, 38, and 83?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) deposition notice.
306	252:15-18	And is CHO-cell-produced EPO glycosylated on any other amino acids?	DR. LOEB: Outside the scope of the 30(b)(6) notice.
307	252:22-253:2	The four we talked about: asparagine 24, asparagine 38, asparagine 83, and serine 126?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice.
308	253:6-11	Are any other amino acids in the CHO-cell-produced EPO post-translationally modified by the CHO cell?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice. Calls for expert testimony.
309	253:17-22	What other amino acids of human erythropoietin are post-translationally modified when produced in a CHO cell?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice. Calls for expert testimony.
310	254:2-8	Are there any other post-translational modifications to human EPO produced in a CHO cell?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and our designation. Calls for expert testimony.
311	254:12-21	Before lunch, I think you said the process of -- in a cell to make a protein is called translation rate. So, I mean, any process after that that modifies the protein made by that process.	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice. Calls for expert testimony. And mischaracterizes the witness's previous testimony.
312	255:16-256:2	When human EPO is produced by a CHO cell, are there any amino acids that are changed after the time the amino acids are translated into a polypeptide -- DR. LOEB: Objection.	DR. LOEB: Objection. Outside the scope of the 30(b)(6) designation and calls for expert testimony.

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		Outside --	
		BY MR. JAGOE:	
		Q -- other than the four that we talked about that are glycosylated?	
313	256:4-7	And other than the cleavage of the amino acid 166.	DR. LOEB: Maintain my objection. And compound in the extreme.
314	256:11-17	Erythropoietin isolated from human urine has the same modifications as the ones we just described; right?	DR. LOEB: Objection. Calls for expert testimony outside of the 30(b)(6) designation. Vague and ambiguous. Urinary erythropoietin [sic].
315	257:3-7	What did you mean by "carbohydrate consensus sequence"?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) designation and calls for expert testimony.
316	257:19-25	Just to break down that last answer a little bit, it's a sequence that is necessary for the mammalian host cell to glycosylate an asparagine?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) designation and calls for expert testimony.
317	258:3-8	And those same consensus sequences are in erythropoietin isolated from human urine?	DR. LOEB: Objection. Outside of the scope of the 30(b)(6) designation and calls for expert testimony.
318	258:14-21	The consensus sequence that's direct glycosylation of asparagines in CHO-cell-produced erythropoietin are the same and present in the erythropoietin isolated from human urine?	DR. LOEB: Objection. Outside of the 30(b)(6) notice and designation and calls for expert testimony.
319	259:8-25	CHO-cell-produced EPO is glycosylated on asparagine 24, asparagine 38, asparagine 83, and serine 126; correct?	DR. LOEB: Objection. Calls for expert testimony. Compound and outside of the notice and designation under 30(b)(6). THE WITNESS: I can't answer your question. BY MR. JAGOE: Q Why not? A Because you're not specifying the species of EPO. Q Oh. Human EPO. DR. LOEB: Objection.

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			Outside of the scope of the 30(b)(6) notice and designation. Calls for expert testimony.
320	260:9-15	Human EPO produced by a CHO cell is glycosylated on asparagine 24, asparagine 38, asparagine 83, and serine 126; correct?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and designation and calls for expert testimony and compound.
321	260:18-24	And human EPO that has been isolated from human urine is also glycosylated on the same amino acid residues; right?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and designation and calls for expert testimony.
322	261:7-15	In your declaration to the Patent Office, were you telling the Patent Office that the difference between CHO-cell-produced EPO and EPO isolated from human urine was a difference based on the position of where the carbohydrates are attached to peptide?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and vague and ambiguous.
323	261:18-25	Were you telling the Patent Office that the carbohydrate types were different on CHO-cell- produced human EPO and human EPO isolated from human urine?	DR. LOEB: Objection. With respect to carbohydrate types, it's vague and ambiguous, and it's outside the scope of the 30(b)(6) notice.
324	262:13-24	Does the declaration that you submitted to the Patent Office explain that the physical properties of recombinant human EPO are within the error of the methods of analysis indistinguishable from those of urinary human EPO and that only in the case of the fine structure of the carbohydrate moieties can a distinction between recombinant human EPO and urinary EPO be defined?	DR. LOEB: Objection. Compound. But also outside of the 30(b)(6) notice and designation.
325			
326	263:11-264:3	R. JAGOE: You're right. I'm reading from AM-ITC 00092856. And it says that, "Even this difference is quantitative, rather than qualitative, while the relative proportions of	DR. LOEB: Objection. It's outside of the scope of the 30(b)(6) notice. And it would be ever so much easier to get an answer to this question, if you were

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		the carbohydrate moieties are somewhat different, all of the carbohydrate structures found in recombinant human EPO are also found on urinary human EPO."	to put the document in front of the witness so he could read it for himself.
		BY MR. JAGOE:	
		Q Is that a true statement?	
327	264:12-265:3	Is it true that the differences between recombinant human EPO and urinary human EPO are quantitative rather than qualitative and the relative proportions of the carbohydrate moieties are somewhat different, all of the carbohydrate structures found in recombinant human EPO are also found in urinary human EPO.	DR. LOEB: Let me restate my objection. It's such a long quotation that you're asking that it would be much easier, if he could look at it and give you a fair answer to your question. Outside the scope of the 30(b)(6) notice. But you can answer in his personal capacity after he sees it
328	266:15-21	Does your declaration explain to the Patent Office that the difference between carbohydrate of recombinant EPO and urinary EPO are quantitative, rather than qualitative?	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and designation and vague and ambiguous.
329	267:10-267:19	Q So the declaration contradicts the statement in the PLA on page 765? A I believe there's another -- Q Just look at page 765 and answer this question, and we'll get what you want to look at.	DR. LOEB: And I'll take the opportunity to impress some objections. Outside of the scope of the 30(b)(6) topic and designation.
330	268:19-269:2	Q So you see there's a section on page 765 that we've been talking about, and the first full sentence starts with, "The physical properties of recombinant human EPO . . ." A Yes. Q And your declaration to the Patent Office contradicts that; right?	DR. LOEB: Outside of the scope of the 30(b)(6) notice.
331	269:22-270:7	Q 791, and the second paragraph ends with the sentence, "The sequence data indicate that although the relative proportions differ somewhat between recombinant human EPO and urinary human EPO, they both contain the same	DR. LOEB: Objection. Outside the scope of the 30(b)(6) notice and designation.