

US Patent and Trademark Office

Coalition for Affordable Drugs VI v. Celgene

Video Deposition of: Dr. Jeffrey Fudin, Volume 1 January 7, 2016

Page 1 Page 3 UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD INDEX COALITION FOR AFFORDABLE DRUGS VI, LLC, WITNESS: JEFFREY FUDIN, VOLUME 1 Petitioner, Examination by Mr. Chalson..... 5 V. CELGENE, Patent Owner. Case No.: IPR2015-01092: IPR2015-01096: IPR2015-01102; IPR2015-01103 VIDEO DEPOSITION OF Dr. Jeffrey Fudin, Volume 1 January 7, 2016 Dallas, Texas Lead: Andrew Chalson, Esquire Firm: Quinn Emanuel FINAL COPY JANE ROSE REPORTING 1-800-825-3341 Page 2 Page 4 1 **APPEARANCES** THE VIDEOGRAPHER: Good morning. This 2 begins Videotape No. 1 in the deposition of FOR THE PETITIONER 3 Dr. Jeffrey Fudin in the matter of Coalition for Sarah Spires, Esquire 4 Affordable Drugs VI versus Celgene. Today is Parvathi Kota, Ph.D. 5 January 7, 2016 and the time is 9:09 a.m. This Sadaf Abdullah, Esquire 6 deposition is taking place at the offices of SKIERMONT DERBY LLP 7 Skiermont Derby, LLP. It was made at the request of 2200 Ross Avenue, Suite 4800W 8 Quinn Emanuel, New York. Dallas, Texas 75201 9 I'm Joshua Nation, the videographer. Telephone: 214.978.6613 10 The court reporter is Laurie Carlisle with Jane Rose FOR THE PATENT OWNER 11 Reporting, New York, New York. Counsel, please Andrew Chalson, Esquire. 12 identify yourselves and state whom you represent and Frank Calvosa, Esquire 13 please speak slowly for the court reporter. Quinn Emanuel Urguhart & Sullivan, LLP 14 MS. SPIRES: Sarah Spires on behalf of 51 Madison Avenue, 22nd Floor 15 Coalition for Affordable Drugs, and with me today is New York, New York 10010 16 Parvathi Kota and Sadaf Abdullah. All three of us Telephone: 212.849.7000 17 from the law firm of Skiermont Derby. 18 Gasber LaRosa, Esquire MR. CHALSON: Andrew Chalson from Quinn Emanuel Urquhart & Sullivan in New York on JONES DAY 19 222 East 41st Street 20 behalf of Celgene Corporation. With me is Frank New York, New York 10017 21 Calvosa, also from Quinn Emanuel, and Gasper LaRosa Telephone: 212.326.3939 22 from Jones Day. 23 JANE ROSE REPORTING 24 Laurie Carlisle, CSR, CRR, RMR 25 Joshua Nation, Videographer



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Page 7	Page 5
offered in that case?	JEFFREY FUDIN, 1
A. Yes. In that particular case my opinions	ving been first duly sworn, testified as follows: 2
had to do with some part of a generic equivalent for	EXAMINATION 3
an extended-release oxycodone.	MR. CHALSON: 4
 Q. Do you know if it related to the issue of 	Q. Good morning, sir. 5
infringement?	A. Good morning. 6
A. Yes, it did.	Q. Can you please state your full name and 7
 Q. Did it also relate to issues regarding 	me address for the record?
validity of the patents in suit?	A. Dr. Jeffrey Fudin, F-U-D-I-N. Home address 9
A. I don't remember.	34 Wakefield Court, Del Mar, New York 12054.
Q. Did you testify at trial in that case?	Q. You understand you're under oath today,
A. Well, no. In Canada it was a bit	? 12
different, so the deposition was kind of like a	A. I do. 13
trial.	Q. Is there any reason you can't testify 14
Q. That was the only testimony you gave in the	thfully and accurately today?
case, the deposition?	A. No. 16
A. Yes.	Q. Are you represented by counsel today, sir?
 Q. Have you ever been deposed in connection 	A. Yes. 18
with an IPR before?	Q. Who are you represented by?
A. No.	A. Represented by Skiermont and colleagues. 20
 Q. Just generally cover some ground rules so 	MR. CHALSON: Do you agree with that?
we're on the same page. We're going to have a series	MS. SPIRES: Yes.
or decomposite arrangements are recomposite	MR. CHALSON: You didn't say when you 23
orally so the court reporter can take down your	nounced yourself, so just making sure.
answer. Try not to speak over each other. You	Q. (By Mr. Chalson) Sir, have you been deposed 25
Page 8	Page 6
understand?	fore?
A. Yes.	A. Yes.
Q. We can take a break anytime you'd like.	Q. About how many times?
I just ask that you don't take a break when a	A. Maybe five. 4
question is pending. Okay?	Q. Can you just generally describe the context 5
A. Okay.	those depositions, please?
Q. If I ask you a question and you answer, I'm	A. They were mostly cases either for or 7
going to assume you understood the question. Is that	ainst various clinicians, either a pharmacist 8
fair?	d/or physicians. Some of them were for the 9
	nician; some of them were for the patient. There
A. Yes.	s one deposition in Toronto which was also a patent 11
	o one deposition in refer to writer was also a patent
Q. If you need clarification, please ask.	se.
Q. If you need clarification, please ask.	·
Q. If you need clarification, please ask.A. Okay.Q. Do you have any patents in your name?	se. 12
Q. If you need clarification, please ask.A. Okay.Q. Do you have any patents in your name?	Se. 12 Q. Was the patent case involving a drug 13
 Q. If you need clarification, please ask. A. Okay. Q. Do you have any patents in your name? A. Yes, I do. 	Se. 12 Q. Was the patent case involving a drug 13 oduct? 14
 Q. If you need clarification, please ask. A. Okay. Q. Do you have any patents in your name? A. Yes, I do. Q. Can you describe, please? A. I have a well, a patent pending. I 	Se. 12 Q. Was the patent case involving a drug 13 oduct? 14 A. Yes, it was. 15
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 Q. If you need clarification, please ask. A. Okay. Q. Do you have any patents in your name? A. Yes, I do. Q. Can you describe, please? A. I have a well, a patent pending. I don't have an actual patent. It's with regard to a product called Urintel. Q. What is Urintel? 	Se. 12 Q. Was the patent case involving a drug 13 oduct? 14 A. Yes, it was. 15 Q. What product? 16 A. OxyContin. 17 Q. Did you represent or did you work with 18
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 Q. If you need clarification, please ask. A. Okay. Q. Do you have any patents in your name? A. Yes, I do. Q. Can you describe, please? A. I have a well, a patent pending. I don't have an actual patent. It's with regard to a product called Urintel. Q. What is Urintel? A. Urintel is a software application that helps clinicians to interpret urine drug screens. 	Se. 12 Q. Was the patent case involving a drug 13 pduct? 14 A. Yes, it was. 15 Q. What product? 16 A. OxyContin. 17 Q. Did you represent or did you work with 18 pbrands or the generics? 19 A. Generic. 20 Q. Do you know specifically which generic? 21
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Page 9 A. There's two others. Q. Do you work with those individuals in a context outside of that patent or just in connection with the patent? A. Just in - well, they're friends of mine. But in connection with the patent, yes. Q. Do you know where in the process that application is at this point? A. It's - we secured patent pending, and I'm probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay. So you mean you're probably not going to found the process that office relating to that filing? A. Just the paperwork for a patent pending. A. Dust the paperwork for a patent pending. A. Correct. Q. Have you received any feedback from the Patent Office relating to that filing? A. Correct. Q. I think you mentioned before that you consider a clinicain to be a pharmacist or a physician. Is that right? Page 10 A. Yes. Q. Can you just generally describe what a clinicain is, in your opinion? A. Cincician is, in your opinion? A. Cincician is, in your opinion? A. Correct. Q. Do you think all pharmacists are clinicans? A. Yes. Q. Do you think all pharmacists are clinicans? A. Yes. Q. Do you think all pharmacists are clinicans? A. Yes. Q. Do you think all pharmacists are clinicans? A. Yes. Q. Do you think all pharmacists are the Fatent Office? A. I do. Q. What do you consider to be preparate infor parters review at the Fatent Office? A. How far back does the question go? A. How far back do				
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4 with the patent? A Just in — well, they're friends of mine. But in connection with the patent, yes. Q Do you know where in the process that application is at this point? A. It's — we secured patente pending, and I'm probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay. So you mean you're probably not going to continue with the prosecution? A. Correct. Q. Have you received any feedback from the Patent Office relating to that filling? A. Just the paperwork for a patent pending. Q. So they accepted the filling; and other than that, you haven't heard? A. Correct. Q. Ithink you mentioned before that you consider a clinician to be a pharmacist or a physician. Is that right? Page 10 A. Yes. Q. Can you just generally describe what a clinician is, in your opinion? A. Yes. Q. Can you just generally describe what a clinician is, in your opinion? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Id. Q. Mand those four separate IPRs relate to two patents wound by Celgene, correct? A. Id. Q. What did you do to prepare for the deposition today? A. How far back does the question go? Q. What did you do to prepare for the deposition today? A. How far back does the question go? Q. What did you do to prepare for the deposition today? A. How far back does the question go? Q. What did you do to prepare for the deposition today? A. How far back does the question go? Q. What did you do to prepare for the deposition today? A. How far back does the question go? Q. What did you consider to be preparation for this deposition, I'd like you to describe it for the record. A. Whatever you consider to be preparation for this deposition, I'd like you to describe it for the record.	2		2	_
But in connection with the patent yes. A. Just in — well, they're friends of mine. But in connection with the patent yes. Q. Do you know where in the process that application is at this point? A. It's — we secured patent pending, and I'm probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay, So you mean you're probably not going to continue with the prosecution? A. Correct. Q. Have you received any feedback from the Patent Office relating to that filing? A. Just the paperwork for a patent pending. Q. So they accepted the filing; and other than that, you haven't heard? A. Correct. Q. Linkink you mentioned before that you consider a clinician is a person that takes care of patents usually directly either in a clinic or in a patient setting. Somebody that has direct patient care. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians; in your opinion? A. Id. Q. You understand that the deposition today concerns sworn declarations that you submitted in connection with four separate inter partes review at the Patent Office? A. I do. Q. What did you do to prepare for the deposition, I'd like you to describe it for the record. Q. What did you do to prepare for the deposition, I'd like you to describe it for the record. A. How far back does the question go? A. How far back does the form the patent office. A. How far back does the farm the farmacian data that was yesterday? A. It net with them — no. About half a day yesterday. A. It does.	3	context outside of that patent or just in connection	3	A. Okay. So in the last day I sat with
8 But in connection with the patent, yes. 7 Q. Do you know where in the process that application is at this point? 8 A. It's — we secured patented. 9 A. It's — we secured patented. 10 Q. Why do you say that? 11 A. Because that's what my counsel advised me, not to patent it. 12 A. Because that's what my counsel advised me, not to patent it. 13 not to patent it. 14 Q. Okay. So you mean you're probably not going to continue with the prosecution? 15 going to continue with the prosecution? 16 A. Correct. 17 Q. Have you received any feedback from the Patent Office relating to that filling? 18 A. Just the paperwork for a patent pending. 19 A. Just the paperwork for a patent pending. 20 Q. So they accepted the filing; and other than tat, you haven't heard? 21 A. Correct. 22 Q. I think you mentioned before that you consider a clinician to be a pharmacist or a physician. Is that right? Page 10 Page 10 Page 10 Page 10 Page 10 A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians? A. I do. Q. You understand that the deposition today concerns sworn declarations that you submitted in connection with four separate inter partes review at the Patent Office? A. I do. Q. What did you do to prepare for the deposition, I'd like you to describe it for the record. Q. What did you do to prepare for the deposition, I'd like you to describe it for the record. A. What leave you consider to be preparation for this deposition, I'd like you to describe it for the record. A. How far back does the question go? Q. What died you do to describe it for the record. A. How far back does the question go? Q. What died you do to describe it for the record. A. How far back does the question go? Q. What died you do to describe it for the record. A. It does.	4	with the patent?	4	counsel. We discussed various documents, all of
a application is at this point? A. It's – we secured patent pending, and I'm probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay. So you mean you're probably not going to have you received any feedback from the Patent Office relating to that filing? A. Just the paperwork for a patent pending. Q. So they accepted the filing; and other than that, you haven't heard? A. Correct. A. Correct. A. Correct. A. Correct. A. Cyrea. A. Yes. Q. Can you just generally describe what a clinician is, in your opinion? A. Clinician is a person that takes care of patients usually directly either in a clinic or in a patient setting. Somebody that has direct patient care. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you understand that the deposition today connects on with four separate inter partes review at the Patent Office? A. Ido. Q. What did you do to prepare for the deposition, I'd like you to describe to be preparation for this deposition, I'd like you to describe to be preparation for this deposition, I'd like you to describe to be preparation for this deposition, I'd like you to describe to be preparation for this deposition, I'd like you to describe the record. A. Correct. Q. Do you think all pharmacists are clinicians? A. Yes. Q. Do you think all pharmacists are clinicians. A. I'do. Q. You understand that the deposition today connects sworm declarations that you submitted in connection with four separate IPRs relate to two patents owned by Celgene, correct? A. Correct. Q. What did you do to prepare for the deposition, I'd like you to describe it for the record. A. What did you do to prepare for the deposition, I'd like you to describe it for the record.	5	 A. Just in well, they're friends of mine. 	5	which I presume you have. Before that, I spent time
application is at this point? A. It's – we secured patent pending, and I'm probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay, So you mean you're probably not going to continue with the prosecution? A. Correct. A. List — we secured patent pending, and I'm probably not going to continue with the prosecution? A. Correct. A. Correct. A. List — we secured patent pending, and I'm preparation for my - whats is called, my - my report. Okay, And then before that, communications strom, I believe, Paul Skiermont, who contacted me by e-mail. And that's about it. I mean, mostly computer searches and reviewing documents. A. List — we secured patent pending, and I'm preparation for my - whats is called, my - my report. Okay, And then before that, communication was from, I believe, Paul Skiermont, who contacted me by e-mail. And that's about it. I mean, mostly computer searches and reviewing documents. A. List the paperwork for a patent pending. A. Correct. Page 10 Page 12 Page 10 Page 12 A. Yes. Q. Can you just generally describe what a clinician is, in your opinion? A. Clinician is a person that takes care of patients usually directly either in a clinic or in a patient setting. Somebody that has direct patient care. Q. Do you think all pharmacists are cliniclains? Q. Do you think all pharmacists are cliniclains? A. Yes. Q. Do you think all pharmacists are cliniclains? A. Yes. Q. Do you think all pharmacists are cliniclains? A. Yes. Q. Do you think all pharmacists are cliniclains? A. Yes. Q. Do you think all pharmacists are cliniclains? A. Yes. Q. Do you didn't look to see whether or not it was part of the record as it exists today? A. Correct. Q. What did you do to prepare for the deposition today? Q. What did you do to prepare for the deposition today? Q. What did you do to preparate inter parts review at the Patent Office, correct? Q. What did you do to prepare for the deposition today? Q. What did you	6			
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probably not going to have it patented. Q. Why do you say that? A. Because that's what my counsel advised me, not to patent it. Q. Okay. So you mean you're probably not going to continue with the prosecution? A. Correct. A. Yes. C. Can you just generally describe what a clinic or in a patient setting. Somebody that has direct patient care. B. Can op ou think all pharmacists are clinicians? A. Yes. C. Do you understand that the deposition today connecrison with four separate inter partes review at the Patent Office, either with your declaration or with the petitions that were filed. A. Correct. A. Yes. C. Can you understand that the deposition today concerns sworn declarations that you submitted in connection with four separate inter partes review at the patent Office, either with your declaration or with the petitions that were filed. A. Ves. A. Oyou understand that the deposition today concerns sworn declarations that you submitted in connection with four separate inter partes review at the patent Office, either with your declaration or with the petitions that were filed. A. Okay. I have no idea. A. Yes. A. Probably not. Q. You understand that the deposition today concerns sworn declarations that you submitted in the petitions that were filed. A. Okay. I have no idea. Q. You didn't look to see whether or not it was part of the record as it ex	8	application is at this point?	8	articles, looking at the various patents, at the
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7.1 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	23	this deposition, I'd like you to describe it for the	23	-
A. Okay. I'll start with the most recent and 25 Q. Were there any others present?	24	· · · · · · · · · · · · · · · · · · ·	24	•
		1 0 0 0 1 0 1		71. It does.

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	Page 13	Page 15
1	A. No.	1 Q. And the title of the '720 patent is
2	Q. Did you talk to anyone else in preparation	2 "Methods for Delivering a Drug to a Patient while
3	for the deposition today?	3 Avoiding the Occurrence of an Adverse Side Effect
4	A. No.	4 Known or Suspected of Being Caused by the Drug,"
5	Q. Have you ever spoken to anyone who's	5 correct?
6	affiliated with CFAD, the Coalition for Affordable	6 A. Correct.
7	Drugs?	7 Q. You would agree with me, right, that both
8	A. No. Not that I know of.	8 of these patents focus on avoiding adverse events
9	Q. Did you ever speak to Kyle Bass about these	9 associated with drug products?
10	matters?	10 MS. SPIRES: Object to form.
11		11 A. Yes.
	A. I don't know who Kyle Bass is.	7 100.
12	Q. Fair enough. Have you ever spoken to Erich	(=) (=) g g g
13	Spangenberg about these matters?	and the parente are the causty reconcerner.
14	A. Erich Spangenberg sent me an e-mail and,	pharmaceutical prescriptions, right?
15	I think, initially asked me if I would be interested	15 A. I'm not really sure what the question is
16	to speak with him about being an expert. I think I	16 asking.
17	spoke to him once, and that's probably it.	17 Q. Sure. I just want to understand or
18	Q. Do you recall what he said in the e-mail	18 I want to get your understanding of what is really
19	that he sent to you?	the subject matter of the patents. And I'm asking,
20	 A. No, I don't. It's a long time ago. 	in your opinion, the patents don't focus broadly on
21	Q. Do you still have a copy of that e-mail?	21 pharmaceutical prescriptions. Generally, instead,
22	A. I don't know.	they focus on mitigating and avoiding adverse events
23	MR. CHALSON: To the extent you do,	associated with potentially dangerous drugs, right?
24	Counsel, we'd request production of that e-mail.	MS. SPIRES: Object to form.
25	Q. (By Mr. Chalson) You said you reviewed the	A. I'm not sure what you're asking, if you're
		D 40
	Page 14	Page 16
1	patents that are at issue in this proceeding?	asking me you said prescription drugs. I don't
2	patents that are at issue in this proceeding? A. Yes.	asking me you said prescription drugs. I don't really know what you're getting at.
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