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US Patent and Trademark Office

**Coalition for Affordable Drugs VI
v.
Celgene**

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

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<p>UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD ----- COALITION FOR AFFORDABLE DRUGS VI, LLC, Petitioner, 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</p>	<p style="text-align: center;">I N D E X</p> <p>WITNESS: JEFFREY FUDIN, VOLUME 1</p> <p>Examination by Mr. Chalson..... 5</p> <p>Reporter's Certificate..... 395</p> <p>Exhibit Index..... 396</p>
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<p>APPEARANCES</p> <p>FOR THE PETITIONER Sarah Spires, Esquire Parvathi Kota, Ph.D. Sadaf Abdullah, Esquire SKIERMONT DERBY LLP 2200 Ross Avenue, Suite 4800W Dallas, Texas 75201 Telephone: 214.978.6613</p> <p>FOR THE PATENT OWNER Andrew Chalson, Esquire. Frank Calvosa, Esquire Quinn Emanuel Urquhart & Sullivan, LLP 51 Madison Avenue, 22nd Floor New York, New York 10010 Telephone: 212.849.7000</p> <p>Gasber LaRosa, Esquire JONES DAY 222 East 41st Street New York, New York 10017 Telephone: 212.326.3939</p> <p>JANE ROSE REPORTING Laurie Carlisle, CSR, CRR, RMR Joshua Nation, Videographer</p>	<p>1 THE VIDEOGRAPHER: Good morning. This 2 begins Videotape No. 1 in the deposition of 3 Dr. Jeffrey Fudin in the matter of Coalition for 4 Affordable Drugs VI versus Celgene. Today is 5 January 7, 2016 and the time is 9:09 a.m. This 6 deposition is taking place at the offices of 7 Skiermont Derby, LLP. It was made at the request of 8 Quinn Emanuel, New York. 9 I'm Joshua Nation, the videographer. 10 The court reporter is Laurie Carlisle with Jane Rose 11 Reporting, New York, New York. Counsel, please 12 identify yourselves and state whom you represent and 13 please speak slowly for the court reporter. 14 MS. SPIRES: Sarah Spires on behalf of 15 Coalition for Affordable Drugs, and with me today is 16 Parvathi Kota and Sadaf Abdullah. All three of us 17 from the law firm of Skiermont Derby. 18 MR. CHALSON: Andrew Chalson from 19 Quinn Emanuel Urquhart & Sullivan in New York on 20 behalf of Celgene Corporation. With me is Frank 21 Calvosa, also from Quinn Emanuel, and Gasper LaRosa 22 from Jones Day. 23 24 25</p>

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1 JEFFREY FUDIN,
2 having been first duly sworn, testified as follows:
3 EXAMINATION
4 BY MR. CHALSON:
5 Q. Good morning, sir.
6 A. Good morning.
7 Q. Can you please state your full name and
8 home address for the record?
9 A. Dr. Jeffrey Fudin, F-U-D-I-N. Home address
10 is 34 Wakefield Court, Del Mar, New York 12054.
11 Q. You understand you're under oath today,
12 sir?
13 A. I do.
14 Q. Is there any reason you can't testify
15 truthfully and accurately today?
16 A. No.
17 Q. Are you represented by counsel today, sir?
18 A. Yes.
19 Q. Who are you represented by?
20 A. Represented by Skiermont and colleagues.
21 MR. CHALSON: Do you agree with that?
22 MS. SPIRES: Yes.
23 MR. CHALSON: You didn't say when you
24 announced yourself, so just making sure.
25 Q. (By Mr. Chalson) Sir, have you been deposed

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1 before?
2 A. Yes.
3 Q. About how many times?
4 A. Maybe five.
5 Q. Can you just generally describe the context
6 of those depositions, please?
7 A. They were mostly cases either for or
8 against various clinicians, either a pharmacist
9 and/or physicians. Some of them were for the
10 clinician; some of them were for the patient. There
11 was one deposition in Toronto which was also a patent
12 case.
13 Q. Was the patent case involving a drug
14 product?
15 A. Yes, it was.
16 Q. What product?
17 A. OxyContin.
18 Q. Did you represent -- or did you work with
19 the brands or the generics?
20 A. Generic.
21 Q. Do you know specifically which generic?
22 A. The company?
23 Q. Yes.
24 A. It was -- I believe it was Teva.
25 Q. Do you recall generally what opinions you

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1 offered in that case?
2 A. Yes. In that particular case my opinions
3 had to do with some part of a generic equivalent for
4 an extended-release oxycodone.
5 Q. Do you know if it related to the issue of
6 infringement?
7 A. Yes, it did.
8 Q. Did it also relate to issues regarding
9 validity of the patents in suit?
10 A. I don't remember.
11 Q. Did you testify at trial in that case?
12 A. Well, no. In Canada it was a bit
13 different, so the deposition was kind of like a
14 trial.
15 Q. That was the only testimony you gave in the
16 case, the deposition?
17 A. Yes.
18 Q. Have you ever been deposed in connection
19 with an IPR before?
20 A. No.
21 Q. Just generally cover some ground rules so
22 we're on the same page. We're going to have a series
23 of questions and answers. We need you to respond
24 orally so the court reporter can take down your
25 answer. Try not to speak over each other. You

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1 understand?
2 A. Yes.
3 Q. We can take a break anytime you'd like.
4 I just ask that you don't take a break when a
5 question is pending. Okay?
6 A. Okay.
7 Q. If I ask you a question and you answer, I'm
8 going to assume you understood the question. Is that
9 fair?
10 A. Yes.
11 Q. If you need clarification, please ask.
12 A. Okay.
13 Q. Do you have any patents in your name?
14 A. Yes, I do.
15 Q. Can you describe, please?
16 A. I have a -- well, a patent pending. I
17 don't have an actual patent. It's with regard to a
18 product called Urintel.
19 Q. What is Urintel?
20 A. Urintel is a software application that
21 helps clinicians to interpret urine drug screens.
22 Q. Are you the sole inventor of that
23 application?
24 A. No.
25 Q. How many others?

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1 A. There's two others.
2 **Q. Do you work with those individuals in a**
3 **context outside of that patent or just in connection**
4 **with the patent?**
5 A. Just in -- well, they're friends of mine.
6 But in connection with the patent, yes.
7 **Q. Do you know where in the process that**
8 **application is at this point?**
9 A. It's -- we secured patent pending, and I'm
10 probably not going to have it patented.
11 **Q. Why do you say that?**
12 A. Because that's what my counsel advised me,
13 not to patent it.
14 **Q. Okay. So you mean you're probably not**
15 **going to continue with the prosecution?**
16 A. Correct.
17 **Q. Have you received any feedback from the**
18 **Patent Office relating to that filing?**
19 A. Just the paperwork for a patent pending.
20 **Q. So they accepted the filing; and other than**
21 **that, you haven't heard?**
22 A. Correct.
23 **Q. I think you mentioned before that you**
24 **consider a clinician to be a pharmacist or a**
25 **physician. Is that right?**

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1 A. Yes.
2 **Q. Can you just generally describe what a**
3 **clinician is, in your opinion?**
4 A. Clinician is a person that takes care of
5 patients usually directly either in a clinic or in a
6 patient setting. Somebody that has direct patient
7 care.
8 **Q. Do you think all pharmacists are**
9 **clinicians?**
10 A. Yes.
11 **Q. You understand that the deposition today**
12 **concerns sworn declarations that you submitted in**
13 **connection with four separate inter partes review at**
14 **the Patent Office?**
15 A. I do.
16 **Q. And those four separate IPRs relate to**
17 **two patents owned by Celgene, correct?**
18 A. Correct.
19 **Q. What did you do to prepare for the**
20 **deposition today?**
21 A. How far back does the question go?
22 **Q. Whatever you consider to be preparation for**
23 **this deposition, I'd like you to describe it for the**
24 **record.**
25 A. Okay. I'll start with the most recent and

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1 I'll go back, if that's okay.
2 **Q. Fair enough.**
3 A. Okay. So in the last day I sat with
4 counsel. We discussed various documents, all of
5 which I presume you have. Before that, I spent time
6 also reviewing the documents, which required reading
7 articles, searching for some articles, re-reading
8 articles, looking at the various patents, at the --
9 that are in question today, looking at some other
10 patents. For example, the Cunningham patent. Before
11 that, many telephone conversations, many writings in
12 preparation for my -- what's it called, my -- my
13 report. Okay. And then before that, communications.
14 The first communication was from, I believe,
15 Paul Skiermont, who contacted me by e-mail. And
16 that's about it. I mean, mostly computer searches
17 and reviewing documents.
18 **Q. All right. Let's unpack that a little bit.**
19 **I think you first said you reviewed documents?**
20 A. Yes.
21 **Q. And you suggested that you thought I would**
22 **have everything you reviewed. Why do you say that?**
23 A. Well, I don't know that.
24 **Q. Did you review anything that was not**
25 **submitted to the Patent Office, either with your**

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1 **declaration or with the petitions that your**
2 **declaration supports?**
3 A. Repeat that question.
4 **Q. Sure. I'm just trying to understand if, in**
5 **preparing for your deposition, you reviewed any**
6 **materials that were not submitted to the**
7 **Patent Office, either with your declaration or with**
8 **the petitions that were filed.**
9 A. Okay. I have no idea.
10 **Q. You didn't look to see whether or not it**
11 **was part of the record as it exists today?**
12 A. No.
13 **Q. Do you recall specifically everything that**
14 **you reviewed?**
15 A. Probably not.
16 **Q. You also said you met with attorneys.**
17 **I think you said that was yesterday?**
18 A. Yes.
19 **Q. Did you meet with them all day?**
20 A. I met with them -- no. About half a day
21 yesterday.
22 **Q. Does that include the attorneys who are**
23 **here today?**
24 A. It does.
25 **Q. Were there any others present?**

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1 A. No.
2 **Q. Did you talk to anyone else in preparation**
3 **for the deposition today?**
4 A. No.
5 **Q. Have you ever spoken to anyone who's**
6 **affiliated with CFAD, the Coalition for Affordable**
7 **Drugs?**
8 A. No. Not that I know of.
9 **Q. Did you ever speak to Kyle Bass about these**
10 **matters?**
11 A. I don't know who Kyle Bass is.
12 **Q. Fair enough. Have you ever spoken to Erich**
13 **Spangenberg about these matters?**
14 A. Erich Spangenberg sent me an e-mail and,
15 I think, initially asked me if I would be interested
16 to speak with him about being an expert. I think I
17 spoke to him once, and that's probably it.
18 **Q. Do you recall what he said in the e-mail**
19 **that he sent to you?**
20 A. No, I don't. It's a long time ago.
21 **Q. Do you still have a copy of that e-mail?**
22 A. I don't know.
23 MR. CHALSON: To the extent you do,
24 Counsel, we'd request production of that e-mail.
25 **Q. (By Mr. Chalson) You said you reviewed the**

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1 **patents that are at issue in this proceeding?**
2 A. Yes.
3 **Q. These proceedings, I should say. Right?**
4 A. Yes.
5 (Exhibit 1001-case 1092 and 1001-case 1093 marked)
6 **Q. Sir, I'm handing you copies of the '501 and**
7 **the '720 patents that are the two patents at issue in**
8 **these proceedings. And I'll just note for the record**
9 **that the '501 patent is Exhibit 1001 in Case 1092,**
10 **Exhibit 1003 in Case 1096, Exhibit 1003 in Case 1102,**
11 **and Exhibit 1003 in Case 1103. And the '720 patent**
12 **is Exhibit 1001 in all three of the cases -- 1096,**
13 **1102 and 1103. Do you have those in front of you,**
14 **sir?**
15 A. Yes, I do.
16 **Q. Your understanding is that these are the**
17 **two patents that are owned by Celgene that are at**
18 **issue in this proceeding?**
19 A. That's my understanding.
20 **Q. If you could just look at the '501 patent**
21 **for a moment, please. The title of that patent is**
22 **"Methods for Delivering a Drug to a Patient while**
23 **Preventing the Exposure of a Fetus or Other**
24 **Contraindicated Individual to the Drug," correct?**
25 A. Correct.

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1 **Q. And the title of the '720 patent is**
2 **"Methods for Delivering a Drug to a Patient while**
3 **Avoiding the Occurrence of an Adverse Side Effect**
4 **Known or Suspected of Being Caused by the Drug,"**
5 **correct?**
6 A. Correct.
7 **Q. You would agree with me, right, that both**
8 **of these patents focus on avoiding adverse events**
9 **associated with drug products?**
10 MS. SPIRES: Object to form.
11 A. Yes.
12 **Q. (By Mr. Chalson) You'd agree in general**
13 **that the patents aren't broadly focused on**
14 **pharmaceutical prescriptions, right?**
15 A. I'm not really sure what the question is
16 asking.
17 **Q. Sure. I just want to understand -- or**
18 **I want to get your understanding of what is really**
19 **the subject matter of the patents. And I'm asking,**
20 **in your opinion, the patents don't focus broadly on**
21 **pharmaceutical prescriptions. Generally, instead,**
22 **they focus on mitigating and avoiding adverse events**
23 **associated with potentially dangerous drugs, right?**
24 MS. SPIRES: Object to form.
25 A. I'm not sure what you're asking, if you're

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1 asking me -- you said prescription drugs. I don't
2 really know what you're getting at.
3 **Q. (By Mr. Chalson) Well, I think you agreed**
4 **with me a moment ago that the patents focus on**
5 **mitigating and avoiding adverse events associated**
6 **with potentially dangerous drugs, right?**
7 A. That I agree with, yes.
8 **Q. And in general, the concept of**
9 **pharmaceutical prescriptions is much broader than**
10 **that. Right?**
11 MS. SPIRES: Object to form.
12 A. I really don't know what you're asking me.
13 **Q. (By Mr. Chalson) Well, okay. So you know**
14 **what a pharmaceutical prescription is, right?**
15 A. Yes.
16 **Q. And there are -- there are documents out**
17 **there you could look up if you wanted to learn all**
18 **about pharmaceutical prescriptions, right?**
19 A. Yes.
20 **Q. These particular patents have a narrower**
21 **focus than the broad realm of pharmaceutical**
22 **prescriptions, right? They focus on what we've been**
23 **discussing, which is avoiding adverse events**
24 **associated with potentially dangerous drugs, correct?**
25 A. Okay, yes.

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