RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEPTUNE GENERICS, LLC
Petitioner
vs.
ELT LILLY & COMPANY

ELI LILLY & COMPANY Patent Owner

Case Nos. IPR2016-00237 and 00240

SANDOZ, INC.
Petitioner
vs.

ELI LILLY & COMPANY Patent Owner

Case No. IPR2016-00318

Conference Call Held: July 22, 2016

Before: MICHAEL P. TIERNEY and TINA E. HULSE, Administrative Patent Judges

The above-entitled matter came on for conference call hearing on Friday, July 22, 2016 before the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia

REPORTED BY:

KAREN BRYNTESON, RMR, CRR, FAPR

JOB NO: 45556

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 1
      APPEARANCES:
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                                                         APPEARANCES (Continued):
 2
      (ALL PARTIES PRESENT TELEPHONICALLY)
                                                    2
                                                         For Party Teva:
 3
      For Patent Owner Eli Lilly:
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          JOSHUA JAMES, ESQ.
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25
                                                 3
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 1
      APPEARANCES (Continued):
                                                    1
                                                               PROCEEDINGS
 2
      For Party Apotex:
                                                    2
                                                                VIA CONFERENCE CALL
 3
        RAKOCZY MOLINO MAZZOCHI SIWIK, LLP
                                                    3
                                                                          (4:01 \text{ p.m.})
        6 West Hubbard Street
 4
                                                    4
                                                               JUDGE TIERNEY: This is Judge
 5
        Suite 500
                                                    5
                                                           Tierney joining the call. And I also
 6
        Chicago, IL 60654
                                                    6
                                                           have Judge Tina Hulse with me.
 7
        BY: DEANNE M. MAZZOCHI, ESQ.
          dmazzochi@rmmslegal.com
                                                    7
                                                               I have noticed there is a court
 8
          JOHN D. POLIVICK, ESQ.
                                                    8
                                                           reporter on the line. Is that
          jpolivick@rmmslegal.com
                                                    9
                                                           correct?
 9
                                                   10
                                                               THE REPORTER: That's correct,
10
                                                   11
                                                           Your Honor. It's Karen Brynteson.
11
     For Party Mylan:
                                                    .2
                                                               JUDGE TIERNEY: And you are here
12
        ALSTON & BIRD, LLP
13
                                                   13
        90 Park Avenue, 15th Floor
                                                           on behalf of which party?
14
        New York, New York 10016-1387
                                                               THE REPORTER: I am here on
                                                   14
15
        BY: THOMAS J. PARKER, ESQ.
                                                   15
                                                           behalf of Eli Lilly.
          thomas.parker@alston.com
                                                   16
                                                               JUDGE TIERNEY: Okay. Is there
16
                                                   17
                                                           a representative from Eli Lilly on the
17
18
                                                   18
                                                           phone?
      For Party Teva/Fresenius:
19
                                                   19
                                                               MR. GROSSMAN: Yes, Your Honor.
        GOODWIN PROCTER, LLP
20
        The New York Times Building
                                                   20
                                                           This is Dov Grossman from Williams &
21
        620 Eighth Avenue, 8th Avenue
                                                   21
                                                           Connolly. And also with me is David
22
        New York, New York 10018
                                                   22
                                                           Krinsky.
23
        BY: CYNTHIA LAMBERT HARDMAN, ESQ.
                                                   23
                                                               JUDGE TIERNEY: Okay. Welcome
          chardman@goodwinlaw.com
                                                   24
                                                           to the call.
                                                   25
25
                                                               MR. GROSSMAN: Thank you.
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2 (Pages 2 to 5)

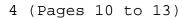


		6		8
1	JUDGE TIERNEY: We have a number		1	that you mentioned in the beginning
2	of inter partes reviews. Let me see		2	JUDGE TIERNEY: Yes.
3	if I have got all the different		3	MR. GROSSMAN: there is also
4	numbers.		4	1191 and 1343. And there are
5	If I have missed one, please		5	actually, Your Honor, for each of the
6	help me out there. They haven't		6	three main proceedings, there is one
7	updated our internal dashboard yet to		7	additional petition and motion for
8	assign certain cases.		8	joinder in each of the proceedings
9	But the numbers I have under all		9	1 0
10	IPRs 2016-00237, 00240, 00318, also		9 10	from another party of Wockhardt, but
11	01340 and 01429. Those are the	‡		they are not participating in today's
12			11	call.
	numbers I have been given. And is	- 1	L2	JUDGE TIERNEY: Could you spell
13	there any others?		L3	that party's name, just so I have it?
14	MS. SPIRES: Yes. For the	-	L4	MR. GROSSMAN: Sure. It is
15	Petitioner, Neptune, there is also	I	L5	W-o-c-k-h-a-r-d-t.
16	2016 for both of these, 01190 and		L6	JUDGE TIERNEY: Thank you.
17	01341.	- 1	L7	MR. GROSSMAN: Would it be
18	JUDGE TIERNEY: Could you repeat	- 1	L8	useful to give you the IPR numbers for
19	the last one, please?	- 1	L9	those as well or is that
20	MS. SPIRES: 0134 I'm sorry,	- 1	20	JUDGE TIERNEY: If you have
21	I gave you the wrong one. Those are	- 1	21	them, I would like it to all be in the
22	two others. I think you have already		22	transcript so we have an idea of all
23	got them. Apologies.	- 1	23	the different parties. And I will see
24	JUDGE TIERNEY: Again, could you	ŧ	24	if they are going to be assigned to
25	repeat those two numbers?	ŧ	25	the same panel or how they are going
		7		9
1	2016-01190?		1	to assign the cases.
2	MS. SPIRES: Yes. Those are the		2	MR. GROSSMAN: Sure. So those
3	two joinder motions.		3	are, again, all IPR-2016. It is 1335,
4	JUDGE TIERNEY: Okay. I have		4	1337, and 1393.
5	not been given on my docket these		5	JUDGE TIERNEY: Thank you. Are
6	numbers yet. That's why I am asking		6	there any additional cases we need to
7	it.		7	be aware of?
8	MS. SPIRES: Okay.		8	Okay. Hearing nothing, we will
9	JUDGE TIERNEY: So that's the		9	now move on.
10	first one. The second one is?	ł	LO	All right. Thank you for
11	MS. SPIRES: 01341.	- 1	11	everyone joining the conference call
12	JUDGE TIERNEY: 01341. Okay.		L2	today. Obviously we have quite a few
13	And apologies, but we our	- 1	13	parties today. I would like to start
14	we have changed electronic docketing	- 1	L3 L4	off with the Patent Owner.
15	systems, and our electronic docketing	- 1	L 1 L5	And we will start on the cases
16		- 1	L6	
17	system internally is still being	- 1	L0 L7	237 and 240, which involve Neptune.
	updated, as we speak. So not	- 1	L / L8	And apologies in advance if I
по		- 4		misstate something, please just
18	everything is available to me at this	1	١ ٨	
19	moment.	- 1	L9	correct me. We have quite a few cases
19 20	moment. MR. GROSSMAN: And, Your Honor,	ļ	20	and quite a few numbers and quite a
19 20 21	moment. MR. GROSSMAN: And, Your Honor, Dov Grossman here. And just, I think,	,	20 21	and quite a few numbers and quite a few parties here. But I would like to
19 20 21 22	moment. MR. GROSSMAN: And, Your Honor, Dov Grossman here. And just, I think, to completely update this, the numbers	,	20 21 22	and quite a few numbers and quite a few parties here. But I would like to start with the 237 and 240 and have
19 20 21 22 23	moment. MR. GROSSMAN: And, Your Honor, Dov Grossman here. And just, I think, to completely update this, the numbers you were just given, 1190 and 1341, I		20 21 22 23	and quite a few numbers and quite a few parties here. But I would like to start with the 237 and 240 and have the Patent Owner, Eli Lilly, give us a
19 20 21 22	moment. MR. GROSSMAN: And, Your Honor, Dov Grossman here. And just, I think, to completely update this, the numbers		20 21 22	and quite a few numbers and quite a few parties here. But I would like to start with the 237 and 240 and have

3 (Pages 6 to 9)

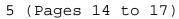


	10	n	12
1			
1	cases. And if there is any motions we	1	discussion.
2	should be expecting that they would	2	JUDGE TIERNEY: For purposes of
3	like to file.	3	today, you can leave those petitions
4	So, Eli Lilly, you are up.	4	and motions for joinder out of the
5	MR. GROSSMAN: Sure. Thank you,	5	discussion. Just thank you for
6	Your Honor. This is Dov Grossman.	6	identifying that there is an
7	I think at this point the only	7	additional set that we need to be
8	thing that I would point out is that	8	aware of.
9	the parties, the Patent Owner and	9	MR. GROSSMAN: Sure. Not a
10	Petitioner, Neptune, have filed	10	problem.
11	stipulations regarding some of the due	11	It is you are correct, Your
12	dates. There was an original one and	12	Honor, that they have raised the same
13	then an updated one that I believe was	13	grounds of patentability. They have
14	filed yesterday.	14	submitted additional expert
15	I don't believe at this point as	15	declarations, in, I believe, perhaps
16	between us and Neptune there are any	16	not all of them, but in the majority
17	issues for the Board. There are, of	17	of them or I think I'm sorry, I
18	course, the pending motions for	18	should say for the Neptune IPRs, I
19	joinder in those proceedings, which	19	believe they have submitted separate
20	our time has not yet run on to respond	20	expert declarations.
21	to.	21	So and I am happy to kind of
22	I don't know whether the Board	22	address the substantive issue as sort
23	wanted to address any of those today	23	of a preview of what our motions would
24	or whether that would come later in	24	be if our oppositions would be if
25	the proceeding, but I think that's	25	now is the appropriate time, or if you
	11	1	13
1	that's the only open issue with	1	prefer to do that later.
2	respect to those two IPRs from our	2	JUDGE TIERNEY: What I would
3	perspective.	3	like to at least get a sense of is do
4	JUDGE TIERNEY: Okay. Before	4	you need a full three months to go
			you need a full timee months to go
5	before we move on to Neptune, I would	5	ahead and have a Patent Owner
5 6	before we move on to Neptune, I would like to understand the brief I saw	5 6	ahead and have a Patent Owner
	•	1	ahead and have a Patent Owner preliminary response or is there a
6	like to understand the brief I saw or sorry I should say the	6	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if
6 7	like to understand the brief I saw	6 7	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the
6 7 8	like to understand the brief I saw or sorry I should say the petitions that I have been able to	6 7 8	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if
6 7 8 9	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and	6 7 8 9	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I
6 7 8 9 10	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to	6 7 8 9 10	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240?
6 7 8 9 10 11	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same	6 7 8 9 10 11	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the
6 7 8 9 10 11 12	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can	6 7 8 9 10 11 12	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional
6 7 8 9 10 11 12 13	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits.	6 7 8 9 10 11 12 13	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who
6 7 8 9 10 11 12 13	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges	6 7 8 9 10 11 12 13 14	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune
6 7 8 9 10 11 12 13 14 15	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of	6 7 8 9 10 11 12 13 14 15	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent
6 7 8 9 10 11 12 13 14 15 16	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases?	6 7 8 9 10 11 12 13 14 15 16	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively
6 7 8 9 10 11 12 13 14 15 16 17	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your	6 7 8 9 10 11 12 13 14 15 16 17	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning
6 7 8 9 10 11 12 13 14 15 16 17 18 19	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step	6 7 8 9 10 11 2 13 14 15 16 17 18	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues
6 7 8 9 10 11 12 13 14 15 16 17 18	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step over any bounds here, those motions	6 7 8 9 10 11 12 13 14 15 16 7 18 9	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues or new evidence that the attorneys for
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step over any bounds here, those motions for joinder are from the Wockhardt	6 7 8 9 10 11 12 13 14 15 16 7 18 19 20 21	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues or new evidence that the attorneys for Neptune would be handling all the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step over any bounds here, those motions for joinder are from the Wockhardt IPRs. And their counsel, of course,	6 7 8 9 10 11 12 13 14 15 16 7 18 18 19 21 22 22	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues or new evidence that the attorneys for Neptune would be handling all the examination and deposition defense,
6 7 8 9 10 11 12 13 14 15 16 7 18 19 20 21 22 23	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step over any bounds here, those motions for joinder are from the Wockhardt	6 7 8 9 10 11 12 13 14 15 16 7 18 9 20 12 22 23	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues or new evidence that the attorneys for Neptune would be handling all the examination and deposition defense, such that, you know, the parties would
6 7 8 9 1 1 1 2 1 3 1 4 1 5 6 7 1 8 9 0 1 1 2 1 2 1 2 1 2 1 2 1 2 2 1 2 2 2 2	like to understand the brief I saw or sorry I should say the petitions that I have been able to identify that have been filed and requests for joinder, they appear to have the same issues and the same exhibits. Are there any cases that you can identify that have a different set of exhibits, different set of challenges to your clients before the 237 cases? MR. GROSSMAN: Sure. And, Your Honor, if I may just, just so it is clear, because I don't want to step over any bounds here, those motions for joinder are from the Wockhardt IPRs. And their counsel, of course, is not on the line, so I want to flag	6 7 8 9 10 11 12 13 14 15 16 7 18 18 19 21 22 22	ahead and have a Patent Owner preliminary response or is there a chance we can expedite this and see if issues are overlapping with the underlying 237 and 240? MR. GROSSMAN: Sure. I understand, Your Honor. I think our view is that to the extent that, for these additional parties who are on the call and who are proposing to join the Neptune proceeding, you know, to the extent that their joinder would effectively be as a silent understudy, meaning that there wouldn't be any new issues or new evidence that the attorneys for Neptune would be handling all the examination and deposition defense,





		.	1.0
	14		16
1	our burden in addressing the main	1	237 and 240?
2	Neptune petition, that under those	2	MR. GROSSMAN: I don't think so,
3	circumstances we would be willing to	3	Your Honor.
4	waive our POPR for those proceedings	4	JUDGE TIERNEY: Okay. Now I am
5	and proceed with those parties, again,	5	going to turn to Neptune on the 237
6	joined as a formal matter but sort of	6	and 240. Counsel for Neptune, are
7	effectively as if they weren't there	7	there any motions that you contemplate
8	from a substantive perspective.	8	filing or anything that you need to
9	I don't know that the parties	9	address?
10	proposing to join the Apotex petitions	10	And we understand there is a
11	and the Teva/Fresenius petitions are	11	joinder issue, but let's start with
12	really that really in disagreement	12	particularly your filing, your case
13	with that position.	13	right now, absent joinder, are there
14	They have tried to sort of	14	any issues we need to discuss?
15	reserve some potential, if there is a	15	MS. SPIRES: This is Sarah
16	unique issue that comes up or reserve	16	Spires from Skiermont Derby on behalf
17	their own expert, if they sort of need	17	of Neptune.
18	it, but I would submit, Your Honor,	18	No, I think counsel for Eli
19	that to the extent that it is the same	19	Lilly, we agree with ^ them there
20	issue, then it is the same grounds of	20	that there are no real issues between
21	patentability, that there wouldn't be	21	the parties. The stipulations have
22	any need for their expert or any need	22	been filed. And we will have a pro
23	for separate ability on their part to	23	hac motion or two that we will file
24	address any issues, the fact that they	24	coming up here in a little bit. We
25	are well represented by Neptune in the	25	don't expect that to be any major
	15	5	17
1	case.	1	issue.
2	JUDGE TIERNEY: Have you been	2	I will note quickly that the
3	able to reach out and have a	3	Wockhardt, I believe, IPR joinder
4	discussion with the parties seeking	4	motions, we have not been served with
5	joinder that you mentioned in	5	those. This is the first I have
6	particular, Apotex and Teva, to see if	6	actually heard of them.
7	they would be willing to enter into a	7	So if they are attempting to
8	joint stipulation?	8	join the Neptune IPRs, if anyone has
9	MR. GROSSMAN: We have not had	9	information about that, that would be
10	that opportunity yet, Your Honor, in	10	great. I am not able I have tried
11	part because the timing for motions to	11	to pull up those three numbers on the
12	join just ran last week. And so we	12	portal system, and it is not showing
13	were sort of waiting for everything	13	anything. So this one is new to us.
14	before we could sort of try to address	$\frac{1}{14}$	JUDGE TIERNEY: Okay. Well, if
15	any parties' stipulations on this	15	you can have that conversation
16	issue.	16	off-line because Wockhardt is not
17	JUDGE TIERNEY: But I take it	$\frac{1}{17}$	actually present and, yeah, I am not
18	you are willing to reach out and have	18	even sure I will be assigned those
19	such a discussion?	19	cases at this point in time.
20	MR. GROSSMAN: We would be happy	20	MS. SPIRES: Okay.
21	to do so, Your Honor.	21	JUDGE TIERNEY: So I would
22	JUDGE TIERNEY: I would	22	rather not get too far into the
23	appreciate it.	23	substance or any details on those
24	Is there anything else we need	24	cases.
25	to discuss from the Patent Owner on	25	MS. SPIRES: Sure.
	Just woo in our tile i attent O Willer Off	77	Mis. Si ikks. Buic.





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