IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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| UCB, INC., UCB PHARMA GMBH, RESEARCH CORPORATION TECHNOLOGIES, INC., and HARRIS FRC CORPORATION, | : | CIVIL ACTION |
| Plaintiffs, | : | |
| v | : | |
| ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD., | : | |
| Defendants. | : | NO. 13-1206-LPS |

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Wilmington, Delaware
Friday, October 17, 2014
*Telephone Conference*

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BEFORE: HONORABLE **LEONARD P. STARK**, Chief Judge

APPEARANCES:

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MORRIS NICHOLS ARSHT & TUNNELL, LLP
BY: JACK B. BLUMENFELD, ESQ., and
PAUL SAINDON, ESQ.

and

COVINGTON & BURLING
BY: GEORGE F. PAPPAS, ESQ.
(Washington, District of Columbia)

Counsel for Plaintiff

SHAW KELLER, LLP
BY: JOHN W. SHAW, ESQ.

and

APPEARANCES: (Continued)

COHEN & GRESSER, LLP
BY: RICHARD G. GRECO, ESQ., and
GURPREET (RAY) SINGH WALIA, ESQ.
(New York, New York)

Counsel for Accord Healthcare, Inc., and Intas Pharmaceuticals, Ltd.

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P R O C E E D I N G S

(REPORTER'S NOTE: The following telephone conference was held in chambers, beginning at 12:52 p.m.)

THE COURT: Good afternoon, everybody. This is Judge Stark. Who is there, please?

MR. BLUMENFELD: Good afternoon, Your Honor. For the plaintiffs, it's Jack Blumenfeld and Paul Saindon from Morris Nichols and George Pappas from Covington & Burling.

THE COURT: Okay.

MR. SHAW: Good afternoon, Your Honor. It's John Shaw for defendant Accord Healthcare; and joining me from Cohen & Gresser are Richard Greco and Ray Walia. Mr. Greco will be presenting the position for the court.

THE COURT: That's fine. I have my court

reporter here. For the record, it is our case of UCB Inc. et al versus Accord Healthcare Inc., Civil Action No. 13-1206-LPS. We're here to discuss Accord's request. It's a motion to compel. So we will hear from Accord and I guess Mr. Greco first. Go ahead, please.

MR. GRECO: Yes. Thank you. Good afternoon, Your Honor. This is Richard Greco for Accord.

Accord brought this motion to compel an answer to an interrogatory that inquires about the plaintiff's contentions concerning issues that relate to anticipation and obviousness. These are issues that based on the evidence the Court will inevitably have to decide in this case.

The patent in this case have claims to a compound called lacosamide, the formula of which we show in our letter in racemic form. The chemical structure of the lacosamide atom consists of two stereoisomers, and the Court may be familiar with stereoisomers from other matters. Essentially, certain compounds like this one have two versions, the same chemical structure but around a particular carbon atom they have different orientations. The analogy is often made to, it's an imperfect analogy to a left hand and a right hand. They both have four fingers and a thumb but they're not superimposable mirror images of each another.

The interrogatory which was based on a request

to admit arise as a certain three pieces of evidence that we will present in this case.

Our first piece of evidence was that the evidence is going to show that the racemic compound was known in the prior art. And we cite the reference, the LeGall reference as a basis for that. It's on pages 133 and 135 where the lacosamide structure is shown. We also have other references, the '301 patent which I mention in the footnote.

Now, we cite the LeGall thesis not because the interrogatory in any way is asking about the LeGall thesis. We cite that to show the questions that we want answered concerning racemic lacosamide are not hypothetical. They are based on the evidence that the defendants will offer in this case, evidence that has been identified very specifically in our invalidity contentions. We're not just asking hypothetically if there was a racemic lacosamide, we intend to offer the evidence indicated.

The second piece of evidence is that these compounds, lacosamide racemic compounds was already identified for use as an anticonvulsant compound. The treatise, the LeGall treatise was about anticonvulsants, and on pages 154 and 155 of that one example, he discloses that the close structural relationship of lacosamide, the racemic lacosamide to another successful anticonvulsant compound,

plus its lipofillicity and certain electron donating compounds of the constituents, all indicate that it suggests that it would have good anticonvulsant activity.

So, once again, the suggestion for using that as an anticonvulsant that is involved in our interrogatory is not hypothetical, it's going to be part of the evidence in this case, and, once again, the traditional evidence in addition to LeGall.

THE COURT: Mr. Greco, let me stop you there. Obviously, I can see this is going to be on the merits; when we get there, an issue that I suppose will be in dispute and as you suggest we will have to resolve, but we're here today on a motion to compel responses to contention interrogatories. It seems like your contention interrogatories are a fairly indirect and arguably premature way to get whatever evidence and contention the plaintiff is going to respond to your arguments with. Tell me why it's wrong for me to see it that way.

MR. GRECO: Well, because it's very specific. One possible defense to the anticipation and obviousness argument would relate to claim 9, which is the only claim which has a requirement of purity at 90 percent R stereoisomer. The plaintiffs couldn't fairly say even though you showed the racemic is in the drug and that the R is preferred in that anticonvulsant, a person of ordinary

skill in the art might not be able to make that 90 percent composition using ordinary skill, and sometimes in some cases involving enantiomers that is the case.

So the request to admit was a very narrow specific fact based request that is exactly the fact issue that will be in dispute. Would a person of ordinary skill in the art, on the date of the patent, with knowledge of this compound, be able to make a composition that is 90 percent by weight of the R stereoisomer using routine skill?

Now, they denied, as they have a right to do, but in the interrogatory, when we inquired as to what the basis of the denial is, apparently they're going to assert that it is not enabled, they told us nothing. They said they're relying on the state of the art; which if we had said our obviousness case relies on the state of the art and nothing more, I don't think anybody would say that is adequate.

THE COURT: All right. Let me interrupt you. What about the argument that what you are really seeking is a legal conclusion which is inappropriate?

MR. GRECO: It's not a legal conclusion. It's a fact issue upon which once decided legal conclusions might be drawn. But whether a person of ordinary skill in the art could use routine skill to make a 90 percent composition is

not a legal question. That is a question of fact that they may have contentions on. I mean we contend that they could because the patent itself says it was routine, well-recognized methods and initially available material.

So we have no idea why they're going to argue, as they apparently are, that this is not enabled. We don't know what references they're going to use, we don't know what arguments they're going to use, and maybe I'm not clever enough to think of any but I certainly can't think of any.

When we depose the inventors in this case and when we depose other people involved in this field at the time and as we prepare our expert report, we need to know what the positions are going to be so we could address it, so we could examine it and find out if it has any basis in fact.

But I have not asked a legal question, which is, is it enabled, which is ultimately the legal conclusion. I ask their position on the fact. And if they admit that fact, then we probably have an issue. If they deny it, well, what is the basis for them saying a person of ordinary skill in the art could not make this composition with routine skill based on the patent.

THE COURT: All right. Thank you. Let me hear from the plaintiff, please.

MR. BLUMENFELD: Your Honor, it's Jack Blumenfeld.

My understanding at least is that the purpose of requests for admission is to narrow issues for trial, not to ask hypothetical questions, and especially hypothetical questions that go to issues of law. Because of the nature of requests for admission and the consequences of admitting something, they obviously have to be very precise. And,

When you look at these requests, they're not narrow, they're not specific, they're not precise. What they ask is what a person of ordinary skill in the art, who is undefined, seek to use the compound as an anticonvulsant, would have preferred, would have been able to create, would have had a reasonable expectation of. Those are not, you know, straightforward precise fact questions.

Whatever the LeGall thesis is and whether or not what it says is hypothetical. The requests for admission are hypothetical, and that is why we objected to them as vague and hypothetical and call for expert opinions and then we denied them.

On the interrogatory, we responded that the hypothetical premises are wrong, that the requests are unsupported, but it's hard to respond to things that provide no context and that are vague. And as we pointed out in our letter, in Accord's letter, and again this morning in

Mr. Greco's presentation, the issue has somehow morphed from these what would a person of ordinary skill in the art at the priority date of the patent have expected, et cetera, to what does the LeGall thesis disclose and is it enabling? That wasn't asked in any request for admission.

We're going to give them our contentions on the specific LeGall thesis, we can do that, but it is 178 page thesis. It does provide context, and there is a lot more to it than just here is a compound and tell us what a person of ordinary skill in the art would or would not have done. We just can't, we can't deal with an interrogatory that says tell us all facts relating to what a person of ordinary skill would have preferred, would have been able to create, would have had a reasonable expectation of if he or she knew of something that apparently nobody other than the inventor did know of, and that is hypothetical, and it seeks expert opinions.

They're going to get our contentions on the LeGall thesis, but I don't think there is any basis for them to come in with these imprecise, broad requests for admission that, as Your Honor said, are rather indirect. If what they wanted to know about was the LeGall thesis, this was a very funny way to ask about it. So we don't think there is any basis to require us to respond to that interrogatory about these imprecise requests for admission.

THE COURT: All right. Help me better understand your further argument that this is really going to a question of law and is I suppose separately improper on that basis as well.

MR. BLUMENFELD: Right. We cited Judge Farnan's *Fulhorst* case, which had a different context but a somewhat similar request for admission, which was admit that something would not infringe if such components were used in a certain structure. He said that is an infringement issue which is a hypothetical question of law.

Apparently, from what I heard this morning, what Mr. Greco or Accord are seeking are admissions that go to whether or not -- in the letter it was enablement, this morning it was obviousness and anticipation.

Again, I think those do call for legal conclusions on hypothetical facts which really aren't spelled out, and for that reason also we shouldn't we required to respond to that interrogatory any more than we have already done.

THE COURT: Okay. Thank you.

Mr. Greco, you can respond.

MR. GRECO: Yes. I'd like to respond briefly to this.

First of all, we're not moving to compel any answer on the request to admit. They denied it and that's end of it. It's on the interrogatory. The way of framing

the interrogatory to get at exactly the factual issue was to use the request to admit as the basis. It's not hypothetical here. Because it looks like what happened in this case, which has already happened, is that we are going to introduce evidence that the racemic compound was known and we're going to introduce evidence that a person of ordinary skill would readily make 90 percent R stereoisomer based on the patent. It was already in the prior art.

If they're going to say they wouldn't be able to do that, that it's not enabled, that something that the inventor taught was the only way to do it, they have to tell us what that is. That is a narrow issue. It's not a legal question. It doesn't ask anything about the law, and it certainly doesn't ask anything about the LeGall thesis. As I mentioned, the reason we cited LeGall was to show when we're talking about racemic lacosamide, we're talking about evidence that we're going to bring as evidence in this case.

So the question of whether the 90 percent stereoisomer composition could be made is very strongly projected by these facts, and it's something they're going to have to address. If they're going to say you can't do it, they must have a reason for saying why that is or references that show that it wasn't enabled or that it couldn't do it.

I didn't phrase the interrogatory in terms of

enablement because I'm asking about the fact that a person of ordinary skill could prepare this based on routine skill in the art. That is exactly the fact.

The case cited by my friend Mr. Blumenfeld is quite a different situation. There, claim construction hadn't even been done, and the party was asking about an infringement of a very complicated electronic device of some kind put in a different context.

This question on the request to admit is exactly the question that will come up in this case as a fact question. Therefore, I think it's clearly chosen fact and it's something that they should have to tell us about.

THE COURT: All right. Thank you. As this is defendant's request for an order to compel the plaintiff to provide something further, and, specifically, to provide a further response to an interrogatory, I'm viewing this as at least initially the burden being on the defendant and having held the defendant to their burden, I find that they have not met it, and I'm denying the relief requested by the defendant.

Simply put, I'm not persuaded by defendant that at this point in this case I should be ordering the plaintiff to do anything further in response to these particular interrogatories. Having looked at the RFAs, the requests for admission that is and the related

interrogatories and the responses, I am of the view that in combination, what is sought is vague, is hypothetical, is not precise, and is not amenable to at least an order requiring the plaintiff to provide anything further than it has at this time.

I also am mindful of where we are in the schedule in this case. I'm confident, and, in fact, it's really been represented by the plaintiff that in time, assuming these remain material and disputed factual issues, that the defendant will have all of the information regarding the plaintiff's position that the defendant needs in order to fairly present its own case. So I see in that regard the motion as being really somewhat premature. The experts will be weighing in in due course in this case; and I'm not persuaded that there is really any prejudice to the defendant at this time either.

I'm not reaching the additional grounds for the plaintiff to oppose the motion which is whether or not these interrogatories should be viewed as going to legal conclusions. I don't really need to reach that issue in this case. I have said enough to explain why my ruling is that I'm denying the request from the defendant.

Are there any questions about any of that, Mr. Greco?

MR. GRECO: No, sir.

THE COURT: And Mr. Blumenfeld?

MR. BLUMENFELD: No, Your Honor. Thank you.

THE COURT: All right. Thank you all very much for your time. Good-bye.

(Telephone conference ends at 1:10 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Brian P. Gaffigan
Official Court Reporter
U.S. District Court