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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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STEADYMED LTD., STEADYMED THERAPEUTICS, INC., and
STEADYMED U.S. HOLDINGS, INC.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner.

-----X

DATE: October 6, 2016

TIME: 2:01 p.m.

TELEPHONIC CONFERENCE CALL BEFORE the
Panel among the respective parties, before
LA TONIA C. LEWIS, RPR, a Notary Public of the
State of New York.

JOB NO. 114034

1
2 APPEARANCES:

3
4 DLA PIPER

5 Attorneys for the Petitioner
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7 New York, New York 10020
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9 LISA HAILE, ESQ.
10 MYA CHOKSI

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13 FOLEY & LARDNER

14 Attorney for the Patent Owner
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17 Washington, D.C. 20007
18 BY: STEPHEN MAEBIUS, ESQ.
19 GEORGE QUILLIN, ESQ.

20
21 United Therapeutics
22 1735 Connecticut Ave NW
23 Washington, D.C. 20009
24 BY: SHAUN SNADER
25

1 Proceedings

2 JUDGE HARLOW: Good afternoon.
3 This is Judge Harlow. Is counsel for UTC
4 on the line?

5 MR. SNADER: This is Shaun Snader,
6 counsel for UTC. And I'm expecting at
7 least a couple of more people to join.

8 JUDGE HARLOW: We'll wait just a few
9 minutes for your counsel to get on the
10 line.

11 MS. HASPER: This is Katherine
12 Hasper from Wilson Sonsini on behalf of
13 United Therapeutics. I joined while Shaun
14 was talking to you.

15 JUDGE HARLOW: It sounds like
16 everybody's here. Judges Green, Chang,
17 and Harlow are also on the line. This is
18 a conference call in IPR 2016-00006,
19 Steadymed versus United Therapeutics
20 concerning United Therapeutics' request
21 for authorization to file a motion to
22 strike portions of Steadymed's reply and
23 currently filed expert declaration as well
24 as UTC's request to file a -- certified
25 responses to Steadymed's reply.

1
2 APPEARANCES: (Continued)

3
4
5 WILSON SONSINI GOODRICH & ROSATI
6 Attorney for United Therapeutics
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8 Washington, D.C. 20007
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15 Administrative Patent Judges:
16 Judge Harlow
17 Judge Green
18 Judge Chang
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1 Proceedings

2 Will counsel for Steadymed, please,
3 identify themselves?

4 MR. POLLACK: Good afternoon, your
5 Honor. This is Stuart Pollack from DLA
6 Piper in New York. I represent petitioner
7 Steadymed. I am also joined from my
8 office by Mya Chocksi, who is just going
9 to be listening in for educational
10 purposes.

11 MS. HAILE: And also Lisa Haile with
12 DLA Piper.

13 JUDGE HARLOW: Thank you. And will
14 UTC please identify themselves.

15 MR. MAEBIUS: Good afternoon, your
16 Honor. This is Steve Maebius with Foley &
17 Lardner on behalf of patent owner, UTC.
18 And I'm here with George Quillin as well
19 in my office.

20 MR. TORCZON: And Richard Torczon
21 from Wilson Sonsini is also on the line.

22 MS. HASPER: As is Katherine Hasper
23 also from Wilson Sonsini.

24 JUDGE HARLOW: Thank you. And it
25 appears as well that we have a court

1 Proceedings
2 reporter on the line. Is there anyone
3 else who hasn't been identified at this
4 time?

5 MR. SNADER: I believe, you have my
6 name. But this is Shaun Snader, counsel
7 for United Therapeutics.

8 JUDGE HARLOW: Thank you,
9 Mr. Snader. Mr. Maebius, why don't you
10 get started. Would you please elaborate
11 on UTC's request for authorization to file
12 a motion to strike and/or certify.

13 MR. MAEBIUS: Yes, thank you, your
14 Honor. The first issue we wanted to raise
15 is the new arguments that were presented
16 in the Rogers' declaration. They go
17 beyond the scope of the patent owner's
18 response. And, specifically, we're
19 concerned about paragraphs 44 to 48 as
20 well as paragraphs 60 to 63, which
21 presents new arguments related to terminal
22 gravimetric analysis, new arguments about
23 PXRD pattern, and the new argument that's
24 based on only the melting point of point
25 A, which wasn't addressed in the patent

1 Proceedings
2 owner's response.

3 And I'd like to point out in another
4 interparty's review of IPR 2015-01786. In
5 that case, the board noted that they have
6 discretion to strike or alternatively
7 consider patent owner's position regarding
8 new argument and certify omission for
9 observation or during an oral hearing. So
10 I'd like to more broadly raise the point
11 that we believe we should be allowed to
12 reply in some way to these new arguments
13 if they're going to remain in the record
14 in the Rogers' declaration. The second
15 issue we wanted to raise really to the
16 corporation by reference of various
17 paragraphs in the Rogers' declaration
18 that's not addressed anywhere in the
19 petitioner's reply. And, specifically,
20 under this issue, we would like to point
21 out paragraphs 23 to 48, 53 to 63, 65 to
22 73, and 75 to 83, and 85 to 88. None of
23 those paragraphs are discussed in the
24 petitioner's reply although certain
25 isolated paragraphs are cited in the

1 Proceedings
2 petitioner's reply that refer to the
3 conclusions arising from those paragraphs.
4 And given that petitioner's reply was
5 right up against the board limit, we
6 maintain that this inclusion of so many
7 additional arguments in the declaration of
8 Rogers is an improper incorporation by
9 reference. And I'd like to point out in
10 another interparty's review, IPR
11 2014-00454 at paper number 12, page ten,
12 that was a similar situation in which the
13 board decided that it would not consider
14 the arguments that weren't discussed in
15 the papers filed by the petitioner when
16 there were expenses, additional arguments
17 in the petition not discussed that were in
18 the declaration but not discussed in the
19 petition.

20 And then the third issue that patent
21 owner wishes to raise on this call, is
22 certain mischaracterizations of our
23 expert, Dr. Williams' testimony in the
24 petitioner's reply. And I won't go
25 through every single example of that, but

1 Proceedings
2 one example is on page seven of the
3 petitioner's reply where there is a
4 passage from Dr. Williams' testimony which
5 was clarified during redirect. And in
6 another stipulation that was similar to
7 this IPR 2013-00358, the patent owner had
8 requested an opportunity to file
9 observations on its own expert in that
10 case because petitioner's reply had
11 mischaracterized the testimony. And the
12 patent owner pointed out that it would be
13 prejudicial because there was no other
14 opportunity for patent owner to file a
15 paper addressing this type of situation.
16 And so in this IPR, the board did agree
17 that it would receive a list of the
18 citations to the transcript where it was
19 mischaracterized. And further allowed the
20 patent owner at the oral hearing to
21 present other parts of the deposition
22 testimony that clarified the
23 mischaracterized part.

24 So we would ask that the board give
25 us an opportunity in that IPR 2013-00358

Proceedings

1 to address these mischaracterizations.

2
3 JUDGE HARLOW: Thank you,
4 Mr. Maebius. In recognition of your
5 comment regarding the board having
6 decisions in the past that allow any
7 patent owner to file a list identifying --
8 and since you discussed portions of
9 testimony or in other cases, portions of
10 replies that allegedly exceed the scope of
11 the patent owner response, I was wondering
12 if you could comment on whether UTC would
13 be comfortable with, instead of allowing
14 various motions and surreplies -- and it
15 sounds like now, a request for
16 authorization to file observations. If
17 UTC would be comfortable with following
18 that list approach where the panel would
19 allow UTC to submit a list identifying
20 instances of the claims -- arguments
21 exceeding scope of the patent owner
22 response or mischaracterizations of
23 testimony that both identify the location
24 of the item with which you have issue and
25 a short description thereof and then

Proceedings

1 permitting a response from the petitioner
2 explaining why, in fact, the item doesn't
3 exceed scope or in the case of the
4 testimony why the characterization is not
5 accurate. Would UTC be comfortable with
6 an approach like that?
7

8 MR. MAEBIUS: If that was going to
9 be presented in the context of considering
10 whether it would be struck from the
11 record, I think we would be comfortable
12 with that approach. But if it's not
13 struck from the record, then I think the
14 patent owner should be allowed to reply in
15 some way because these are really new
16 arguments relying on different pieces of
17 evidence. And so we feel we should be
18 able to address it with our own evidence.

19 JUDGE HARLOW: Understood. And when
20 you say address it with your own evidence,
21 are you envisioning, specifically, in a
22 surreply or you had mentioned in your
23 discussion that the other parties had been
24 allowed to address things with oral
25 arguments. Would that be sufficient?

Proceedings

1 MR. MAEBIUS: I think in the case of
2 the Rogers' paragraphs that reflect the
3 arguments, we would need to address it
4 with a surreply and a declaration from our
5 own expert. In the case of the
6 mischaracterized testimony, it would
7 simply be a matter of pointing out other
8 parts of the deposition transcript that
9 clarified it.

10
11 JUDGE HARLOW: Understood. Thank
12 you. Mr. Pollack, would you like to
13 respond?

14 MR. POLLACK: Thank you, your Honor.
15 This is Stewart Pollack on behalf of the
16 petitioner, Steadymed. This is just an
17 attempt to either, one, get a -- get the
18 last word in on these issues or two, you
19 know, make further argument on arguments
20 in our reply that were completely
21 responsive to the patent owner's response.
22 I would first like to point out, I think I
23 understood Mr. Maebius correctly. He's
24 not saying there are any new arguments in
25 the petitioner's reply, he's only saying

Proceedings

1 that he feels that the declaration,
2 somehow raised new arguments, but not the
3 reply itself. So the only complaint about
4 the reply that I heard here, I believe, is
5 that they didn't like how Dr. Williams'
6 testimony is characterized. And he gave
7 an example of page seven of our reply, so
8 I took a look there. And we don't
9 actually characterize Dr. Williams'
10 testimony there, we quote it. So it's
11 there quoted in full. And he doesn't like
12 what's said.
13

14 And he says, well, in our -- in
15 their redirect they led him to try to
16 answer differently. And I looked at page
17 seven, which had to do with whether or not
18 Dr. Williams knew what process was used to
19 make certain cherry-picked processes --
20 whether they were, in fact, the Moriarty
21 prirog (phonetic) or otherwise. And they
22 are saying he said something different in
23 redirect. In fact, he was recrossed on
24 that issue. And in response to that his
25 testimony which is an exhibit, 2059, his

Proceedings

deposition which was submitted in full, pages 27023 to 27012. He said, I simply just don't know how these ten cherry-picked points were made. So there's really -- it's not a mischaracterization. It is what he said, we simply quoted it. We left it there for the court to decide what their interpretation is and exactly what he said it is. So it is not a mischaracterization. Numerous board decisions, I've looked, they've denied these kind of motions to strike including denying even the -- as we're doing here, the opportunity to file the motion to strike.

As stated in one of those decisions, Texas Instruments versus Unified Scientific Batteries. That's IPR number 2013-00213. It's paper number 27 dated April 27, 2014, at 3 in an opinion that Judge Chang was involved in. The board there said a motion to strike is not ordinarily a proper mechanism for raising

Proceedings

the issue of whether a reply or reply evidence is beyond the proper scope permitted under the rules. And that's, you know, what the board has said uniformly in numerous decisions I've seen. I don't recognize their other panels. That's not necessarily precedential, but across the board that's been what the panel decisions have said.

In that decision, the patent owner's similarly complained that the petitioner's use of deposition testimony mischaracterized, but as the board said, and this is a quote, "Motion to strike regarding this issue is not warranted as we are able to evaluate testimony in context and determine what weight, if any, it should be given". That's at paper number 27 in that proceeding at page four. That was IPR 2013-00213.

Let me move to striking Dr. Rogers' declaration. We raised in our petition that the melting point of the Ferri's was higher than the melting point in the 393

Proceedings

patent at issue. And that that meant that the polymorphs was at least as pure, if not purer than the 393 patent that was in Dr. Wingler's declaration as well. Much to Steadymed's surprise, patent owner expert, Dr. Williams came back and said you can't compare melting points of polymorphs. Now, at his deposition he conceded -- Dr. Williams conceded that his basis for that was his personal experience. He didn't have any articles or references. We came back with a declaration from Dr. Rogers who is an expert on polymorphs stating that the melting points of polymorphs can be compared for their purity.

That is the -- the argument that was raised in our petition, which they opposed and which he is replying with. So it's not a new argument. And they should have anticipated that we would do that in response to their questioning Dr. Wingler's opinion on this issue. In regards to arguments that were not in the

Proceedings

reply, you know, we asked United Therapeutics which arguments they were referring to. And they referred to nearly every paragraph in his declaration including his qualifications, the materials reviewed, the summary of his opinion.

Now, when I pointed it to him -- we pointed out to him that that they're including the qualification material as considered and the summary of opinions, they've withdrawn those objections. So they have no problem with the summary of opinion or the materials considered. The only parts or conclusions he draws -- the only parts they're objecting to now are in some sections in order to introduce a topic. He explains, for example, what is a crystal? What is a polymorph? What do those words mean? He did say things like that we believe it would be helpful for the board to understand some of the language used in our reply and in his conclusions.

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