

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

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STEADYMED LTD., STEADYMED THERAPEUTICS, INC.

6 and STEADYMED U.S. HOLDINGS, INC.

7 Petitioner

8 v.

9 UNITED THERAPEUTICS CORPORATION

10 Patent Owner

11

12 Case No. IPR2016-00006

13 Patent No. 8,497,393

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17 TELEPHONIC CONFERENCE CALL

18 January 3, 2018

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24 Reported by: Mary Ann Payonk

25 Job No. 135750

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5 January 3, 2018
6 2:00 p.m.
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8 TELEPHONIC CONFERENCE CALL BEFORE the
9 Panel among the respective parties, reported by
10 Mary Ann Payonk, CA-CSR, Certified Realtime
11 Reporter.
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1 BEFORE ADMINISTRATIVE PATENT JUDGES:
2 Judge Jacqueline T. Harlow
3 Judge Lora M. Green
4 Judge Joni Y. Chang
5

6 ON BEHALF OF PETITIONER:
7 LISA HAILE, ESQUIRE
8 STUART POLLACK, ESQUIRE
9 DLA PIPER
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12 ON BEHALF OF PATENT OWNER:
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17 Washington, D.C. 20007

18 ON BEHALF OF UNITED THERAPEUTICS:
19 RICHARD TORCZON, ESQUIRE
20 BOBBY DELAFIELD, ESQUIRE
21 WILSON SONSINI GOODRICH & ROSATI
22 1700 K Street, N.W.
23 Washington, D.C. 20007

24 ALSO PRESENT:
25 Shaun Snader, United Therapeutics

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2 JUDGE HARLOW: Good afternoon.
3 This is Judge Harlow. Judges Green and
4 Chang are also on the line. We are
5 going to have a conference call with in
6 IPR2016-00006, SteadyMed versus United
7 Therapeutics. Is there a court reporter
8 on the line?

9 MR. MAEBIUS: Yes, there is, Your
10 Honor.

11 JUDGE HARLOW: Thank you. Today we
12 are going to discuss Petitioner's
13 request for authorization to file a
14 motion asking the Board to take
15 jurisdiction over continuing
16 applications under 37 CFR 42.76. With
17 that introduction, counsel for
18 Petitioner, will you please introduce
19 yourself and anyone you might have on
20 the line with you.

21 MR. POLLACK: Thank you, Your
22 Honors, and happy New Year. This is
23 Stuart Pollack for Petitioner SteadyMed.
24 I'm going to be the only one on the line
25 for SteadyMed.

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2 MS. HAILE: Actually, Stuart, Lisa
3 Haile is also on the line with
4 SteadyMed.

5 MR. POLLACK: Oh, okay. I'm sorry.
6 I stand corrected.

7 MS. HAILE: That's okay.

8 JUDGE HARLOW: Thank you,
9 Mr. Pollack and Ms. Haile. Patent
10 Owner, would you please introduce
11 yourself and any colleagues you might
12 have on the line?

13 MR. MAEBIUS: Yes, Your Honor.
14 This is Steve Maebius from
15 Foley & Lardner, and I have George
16 Quillin with me here as well. And also
17 Shaun Snader is on the line from United
18 Therapeutics, and Bobby Delafield and
19 Richard Torczon from Wilson Sonsini.

20 JUDGE HARLOW: Thank you very much,
21 Mr. Maebius. With that, Mr. Pollack, if
22 you'd like to address your request for
23 authorization, you may proceed.

24 MR. POLLACK: Thank you, Your
25 Honors. Section 42.73(d)(3) addresses

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 2 the situation we are in now where a
 3 final written decision has been
 4 affirmed, the mandate has issued, no
 5 further appeals may be taken and there
 6 are continuation applications pending on
 7 the patent whose claim's been canceled
 8 in the IPR. And those continuation
 9 application's claims are not patently
 10 distinct from the claims that have been
 11 canceled.

12 I'll discuss the new continuation
 13 claims in a little more detail shortly,
 14 but the examiners issued
 15 obviousness-type double patenting
 16 rejections over the '393 patent claims
 17 in all three of those continuations, and
 18 in the first of those continuations the
 19 patent owner has obviated that objection
 20 by filing a terminal disclaimer.

21 So just turning back to 42.73, you
 22 know, according to its terms, Section
 23 42.73 in Section C authorizes the Board
 24 to provide a recommendation for further
 25 action by an examiner or the director,

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 2 and that's what we're looking for here
 3 is for the Board to take action by
 4 making a recommendation to the examiner
 5 or the director.

6 And I think by recommendation here
 7 I don't think they're making a
 8 suggestion but rather a statement to
 9 them that patentability claims cannot
 10 continue to be pursued in these
 11 continuations.

12 The ability to direct other parts
 13 of the office to take this action is the
 14 only way that the Patent Office can
 15 comply with the Administrative Procedure
 16 Act and the constitution. It's
 17 consistent with the Federal Circuit's
 18 decision in In Re: Deckler. That's
 19 977 F. Sec. 1449 at 1452 from the
 20 Federal Circuit in 1992. There, the
 21 issue was the idea of interference
 22 estoppel but the concept's the same in
 23 that case. In a prior interference, the
 24 Board found that the patent applicant
 25 was not entitled to the claims and then

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 2 the patent applicant tried to get new
 3 claims that were similar but not
 4 patentably distinct. And there, the
 5 Federal Circuit held that the patent
 6 statute intends that only one patent
 7 should issue for one inventive concept.
 8 And since the applicant was not entitled
 9 to the claims for that concept, they
 10 couldn't pursue claims, additional
 11 claims, in their continuation. So it's
 12 very similar here.

13 In fact, the Board has recognized
 14 in In Re: Deckler in a prior IPR in
 15 Smith & Nephew v. Arthrex, that's
 16 IPR2016-0917. In Paper 12 entered on
 17 September 21, 2016, the Board found that
 18 it was necessary to enter an adverse
 19 judgment where the patent owner
 20 disclaimed all the claims in the patent
 21 before institution. The reason why they
 22 did that is otherwise, the estoppel
 23 provision, they said, in 42.70(d)(3)
 24 would not apply and the patent owner
 25 would be able to pursue patentably

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 2 indistinct claims in a continuation.

3 And the Board found that 42.73 in
 4 Deckler precluded claims and
 5 continuations that were not patentably
 6 distinct, so it was addressed once
 7 before by one panel of the Board.

8 But it's really essential under the
 9 APA Act that the Board -- that the
 10 Patent Office not issue inconsistent
 11 rulings. In fact, that's why the APA
 12 was created as the Federal Circuit
 13 acknowledged in In Re: Zurko, 142
 14 F.3rd. 1447 at 1450.

15 So since 42.73 provides a mechanism
 16 for this office to avoid this type of
 17 APA violation, we believe that it's
 18 essential that the Board do so here and
 19 not allow these continuation patents to
 20 stand; otherwise, we think it would be
 21 arbitrary and capricious as the, on the
 22 one hand, the Board -- not only the
 23 Board but the Federal Circuit has
 24 invalidated these claims at the same
 25 time a single examiner has granted them,

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2 is granting them.

3 And recently in an oral argument in
4 the case Xitronix Corporation v.
5 KLA-Tencor, that's Appeal Number
6 2016-2746, on October 2 of last year, at
7 1731 Judge Moore commented in that case
8 where a similar thing happened there
9 with a jury verdict, prior jury verdict,
10 finding claims invalid. And then in the
11 continuation, the patent owner went on
12 to get slightly different claims, slight
13 change of language. Then on the appeal,
14 Judge Moore said how in the world can an
15 examiner have the authority to allow
16 claims in a continuation patent of
17 that -- there's no way the Patent Office
18 could be allowed to do that once they'd
19 been invalidated.

20 Let me address the question of
21 whether or not these claims are
22 patentably distinct. I think the main
23 evidence of that is simply the fact that
24 the examiner himself has found the
25 claims were not patentably distinct.

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2 also add a purity limitation of
3 99.5 percent. Your Honors may remember
4 the pending claim in the '393 patent
5 having the same limitation that was
6 invalidated.

7 So the claims are identical. It's
8 the exact same treprostinil salt made by
9 the exact same process. There were no
10 additional process steps added. And
11 even if there were, remember that in
12 product-by-process claims it's the
13 product which is patented, not the
14 process steps. Adding additional
15 process limitations doesn't change the
16 product.

17 Also, Your Honors may recall that
18 you ruled and the Federal Circuit
19 affirmed that all the process steps
20 anyway were in the prior art.

21 So here's what we're asking for.
22 We're asking that the Board recommend to
23 the director and the examiner to stop
24 these additional continuations to the
25 '393 patent that the owner has recently

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2 And, in fact, in one case a terminal
3 disclaimer was filed. But the only
4 things these claims add is -- it's the
5 same treprostinil salt as in Claim 9.
6 The only limitations that have been
7 added is in the preamble, the phrase
8 "pharmaceutical batch" instead of
9 "product" is used, although apparently
10 "batch" encompasses the product since it
11 is in dependent Claim 5 that calls for
12 the product made from Claim 1.

13 Then there's also some inherent
14 beneficial results that are added, that
15 the compound be stable for storage at
16 ambient temperature. Remember, it's the
17 same salt as made by the claims here,
18 and these are product-by-process claims.

19 And also, there are limitations
20 that a certain amount of product be
21 present. So in Claim 1, it's -- the
22 first one is 2.9 grams and in another
23 one of their patent applications it's 5
24 kilograms, but that's -- the only
25 difference is there are some claims that

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2 filed which violate the requirement in
3 42.73 that continuations having
4 patentably indistinct claims not be
5 prosecuted. That kind of arbitrary
6 action by a single examiner to allow
7 such claims would violate the APA and
8 the reasoning in In Re: Deckler
9 regarding interference estoppel.

10 Why would one really need this?
11 Well, it may appear to just say, well,
12 why don't you just file more IPRs?
13 These patents will be listed in what's
14 called the Orange Book, which will give
15 Patent Owner United Therapeutics a
16 30-month stay once we try to introduce a
17 product. And we are hoping to get our
18 NDA on file soon for that product, so
19 that will initiate a suit later this
20 year. And so having to wait 18 months
21 for another IPR is really not going to
22 help us when we will have a 30-month
23 stay very soon. And this is for a
24 product that's going to be essential for
25 a patient to take new product, but not a

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 2 generic, and it will have some
 3 advantages over United Therapeutics'
 4 products that will be very important for
 5 patients.

6 Your Honors, do you have any
 7 questions?

8 JUDGE HARLOW: Not at this time,
 9 Mr. Pollack. Is there anything else
 10 from Petitioner or shall we move on to
 11 Patent Owner?

12 MR. POLLACK: There's nothing else,
 13 Your Honor.

14 JUDGE HARLOW: Thank you very much.
 15 Mr. Maebius, would you like to respond
 16 to Petitioner's position?

17 MR. MAEBIUS: Why, yes, Your Honor.
 18 With respect to the case where a
 19 terminal disclaimer was filed, I first
 20 want to point out that the courts have
 21 held that filing a terminal disclaimer
 22 does not constitute an admission of
 23 indistinctness.

24 And the second point I'd like to
 25 make relates to an IPR decision

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 2 2014-01240, Paper Number 22, where the
 3 Board denied a request for a similar
 4 motion to suspend continuations. And
 5 although that involved a pending IPR
 6 whereas here we already have a final
 7 written decision, the Board panel in
 8 that decision denied the request to file
 9 the motion based on Section 311(b) and
 10 noted that the scope of an IPR only
 11 relates to the involved patent and not
 12 to a family of patents. And the
 13 statutory language says that an IPR only
 14 applies to a patent using the singular
 15 form of "a."

16 Also, 42.73(c) wouldn't apply here
 17 because the judgment that may include
 18 the recommendation that SteadyMed is
 19 seeking, the word "judgment" has been
 20 defined in Rule 42.2 to mean a final
 21 written decision by a Board. And, of
 22 course, there already has been a final
 23 written decision by a Board.

24 As to 42.73(d)(3), that also is not
 25 applicable because it requires an

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 2 adverse judgment. And the Board has
 3 held in IPR2014-00346 that "adverse
 4 judgment" means an unappealable final
 5 decision which only applies against the
 6 party's claim has actually been canceled
 7 and not merely held unpatentable. And
 8 the Board in that decision was citing to
 9 the Patent Office comments in the
 10 Federal Register 77 FR 48612. So in the
 11 case at hand we are still subject to
 12 further review by the Supreme Court.

13 A related point is that 42.73(d)(3)
 14 shouldn't be applicable because it also
 15 uses the language that there has to be
 16 indistinctness from the claim which has
 17 been, quote, "finally refused or
 18 canceled." And there has been no final
 19 refusal or cancellation until all
 20 possibility of appeal or further review
 21 has been exhausted.

22 The Board really doesn't have
 23 jurisdiction at this point to give
 24 SteadyMed the relief it requests. And
 25 aside from the purely ministerial acts

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 2 of the Patent Office issuing a
 3 certificate under 42.80, there's really
 4 nothing left for the Board to do here.
 5 The final written decision was appealed.
 6 The Federal Circuit affirmed it but did
 7 not remand. The mandate of the Court
 8 issued on December 21 and presumably has
 9 been received by the PTO.

10 I also want to point out that
 11 SteadyMed previously was warned by the
 12 PTO when it filed several Rule 182
 13 petitions in UT's earlier pending
 14 continuations, and in that decision on
 15 the petitions, the PTO pointed out that
 16 35 USC 122(c) requires that the PTO
 17 ensure that no protest or other form of
 18 pre-grant opposition to an application
 19 be initiated after publication without
 20 the express written consent of the
 21 applicant.

22 And that decision further warned
 23 that another inappropriate submissions
 24 might be referred to OED. And this was
 25 a decision by OPLA on January 25, 2017

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