UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED, LTD.,	)	
Petitioner,	)	Case IPR2016-000006
-v-	)	Patent 8,497,393 B2
UNITED THERAPEUTICS CORPORATION,	)	
Patent Owner.	)	

DATE: April 5, 2017

TIME: 1:30 p.m.

TELEPHONIC CONFERENCE CALL BEFORE the Panel among the respective parties, before Gail L. Inghram Verbano, BA, CRR, CLR, RDR, CSR-CA (No. 8635), and Notary Public.

Job No. 122265

A P P E A R A N C E S:

Attorneys for Petitioner:
DLA PIPER US
1251 6th Avenue
New York, New York 10020
BY: STUART POLLACK, ESQ.
LISA HAILE, ESQ.

Attorneys for United Therapeutics:
FOLEY & LARNDER
Washington Harbor
3000 K Street NW
Washington, D.C. 20007
BY: STEPHEN MAEBIUS, ESQ.
GEORGE QUILLIN, ESQ.

ADMINISTRATIVE PATENT JUDGES:
Judge Jacqueline T. Harlow
Judge Lora M. Green
Judge Joni Y. Chang

ALSO PRESENT:
SHAUN SNADER, United Therapeutics

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JUDGE HARLOW: This is a conference call in IPR 2016-00006, SteadyMed versus United Therapeutic. The purpose of today's call is to discuss the SteadyMed Request for Authorization to file a Motion to Request Action by the Board with regard to two new patents that recently issued from continuing applications of the '393 patent.

I understand that the parties have been introducing themselves as they've signed on to the call, but for the benefit of the court reporter, let's go ahead and take roll, starting with the Petitioner.

Will counsel please introduce yourselves, identify anyone else who is present for your side, and then Patent Owner can proceed after that.

MR. POLLACK: Thank you, Your Honor. This is Stuart Pollack on behalf of the Petitioner, SteadyMed. I'm joined by my colleague, Lisa Haile, from the same law firm, DLA Piper.

MR. MAEBIUS: And on behalf of

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Patent Owner, this is Steve Maebius with Foley Lardner, and I'm here with George Quillin; and also Shaun Snader from United Therapeutics Corporation is on the line.

JUDGE HARLOW: Thank you.

Turning to the substance of our call today, SteadyMed appears to seek action by the Board relating to the estoppel provisions of 37 C.F.R. Section 42.7(d)(3).

Is that a fair representation, Mr. Pollack?

MR. POLLACK: Yes, Your Honor.

JUDGE HARLOW: So when you begin to discuss your portion, one thing I'm particularly curious about is how it is that the estoppel provisions are consistent with the idea of retroactively canceling claims in patents that issued prior to the decision by the Board.

I'd also be interested to hear your views on how SteadyMed's request is timely instead of being premature, given that the time to appeal the final written decision

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has not yet expired.

With that, please feel free to address your request.

MR. POLLACK: Thank you, Your Honor. I'm going to address your second question first.

Section 42.7(d)(3) does address the situation we're in now where a final written decision has issued. And that's because, under Section 42.7(d)(3) and under the other regulations and the statute, the claims, in fact, are canceled, having a final written decision answer.

Now, how do I know that? Well, the Supreme Court has said so. The Federal Circuit has said so. In addition, the Patent Office has said so when it promulgated Section 42.7(d)(3).

Let me start with the courts first.

In the Supreme Court decision that we all know and are familiar with, Cuozzo, Speed Tech versus Lee -- that's 136 Supreme Court 2131 from 2016. In numerous

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places it states that the final written decision canceled Cuozzo's claims.

For example, at page 2137 it states that, quote: The statute authorizes judicial review of a final written decision canceling a patent claim.

Similarly, at 2139, ultimately, the Board ordered Claims 10, 14 and 17 of the Cuozzo patent canceled. That's obviously the Board's order, was the final written decision.

At 2143, after arguments before a panel of three of the Board's Administrative Patent Judges, it issues -- that is, the Board -- a final written decision. Perhaps more importantly, a decision to cancel a patent normally has the same effect as a district court's determination of a patent's invalidity. So the Supreme Court consistently describes a final written decision as the place where the claims are canceled regardless of whether there's a subsequent appeal.

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So similarly, the Federal Circuit which, of course, is hearing an appeal at the first instance, has consistently said that the Board has canceled the claims with the final written decision. The examples are numerous so I'm just going to give a few. There's the Belden case, Belden v. Berk-Tek, in 2015, 805F.3d, 1064 at 1072. And they say Belden appeals the cancellation of Claims 1 through 4.

Another example -- and there's many of these -- Dell v. Acceleron, 818 F.3d 1293 in 2016 at 1295, where they say we vacate the Board's cancellation of Claim 20.

And just last week, Intellectual Ventures II, LLC versus Commerce Bank Shares -- that's a decision on March 27th, 2017. It's 2017 WL 113 02320. It's too early for the F.3d reported decision to come out. It says there at star 2, We affirm the Board's cancellation of Claims 26, 28, 30 to 33 in that proceeding. And then at star 4, For

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the foregoing reasons --

JUDGE HARLOW: I apologize for interrupting you, but we're familiar with these cases and we understand that a final written decision cancels claims.

The question I posed is a bit different, and that is premised on the idea that the Federal Circuit can, of course, vacate our final written decision. So although it is the case that our final written decision serves to cancel claims, it's also the case UTC has the opportunity to appeal our decision, which could potentially resolve in the vacatur of our decision.

And what I'm asking is, given that we don't know whether UTC is going to appeal or not, isn't it a bit premature just now to address your request rather than addressing it down the road when the time for UTC to file an appeal has expired?

MR. POLLACK: I'll address this, as it says in the regulation. So the

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regulation says that a claim that is not patently distinct from a canceled claim -- so this is a canceled claim. So the regulation does -- the regulation language does connect to that.

As far as whether there's always a potential appeal, that's true in every lawsuit, whether it's from the Patent Office or from a district court.

But looking at the facts on the ground now, the facts on the ground now are that the claims have been finally canceled.

Can that be turned around on an appeal? Of course, whether it's through the Federal Circuit or ultimately to the Supreme Court. But as things stand now, there is a cancellation, and that's what the regulation refers to, is a -- is a cancellation.

JUDGE HARLOW: We understand that, Counsel. Perhaps it would be more productive to turn back to the first issue, which is that SteadyMed appears to

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be asking the Board to retroactively apply our estoppel provisions.

So perhaps you could address how it is that the estoppel provisions of Section 42.7(d)(3) would permit us to cancel issued claims, because that does not appear to be at all contemplated by the estoppel provisions.

MR. POLLACK: Okay. Obviously I disagree with you on that, but the reason is as follows.

Under the Administrative Procedure Act, an administrative agency is not really permitted to issue inconsistent opinions at the same time. That's why, in fact, the act was originally created back in the '30s.

If you look at In Re: Zurko, Federal Circuit case going through the history of the APA, at 142 F.3d, 1447 and 1450, they actually point out that Congress created the APA because it was concerned -- and I'm quoting -- about the lack of uniformity and consistency in and among

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the administrative and judicative --

JUDGE HARLOW: Counsel -- Counsel, we also understand the APA. I would appreciate it if you could fast forward to our question, which is, again, two patents issued; and then those patents are not the same as the patent that was subject to IPR and which we subsequently canceled claims for.

So what I'm trying to understand is how it is that the estoppel provisions, which, by their nature, would apply to future action, can be applied to retroactively cancel the claim of different patents that issued prior to our decision in the instant IPR.

MR. POLLACK: Okay. If you look at the regulation, it refers to not only a Patent Applicant but also a Patent Owner. So it's addressing both applications and owners.

Here we have a situation where an agency, within the same week or within even a few weeks, is issuing two decisions

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that are inconsistent. And the whole point of this 42.7(d)(3) is to prevent that. That's why this regulation exists and needs to exist; else, one would have an APA -- a violation and a constitutional violation.

Now, it only applies -- and I think this answers your question -- where the claims are not patentably distinct. And, obviously, on this call I won't be able to show you the claims and why they're not patentably distinct.

What I will tell you about the claims that have recently issued is that not only would they violate the obviousness-type double-patenting bar but they would even violate the statutory double-patenting bar in one case, in the case that issued on March 14th.

The claims are essentially identical other than that the compound formulas have been replaced by their names. So Claim 9 had a formula. The new claims now just say "treprostinil." Claim 9 has a formula

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for benzidine trial. The new claims just say "benzidine trial"; and the word "product" has been replaced with "pharmaceutical composition." And the starting material, it says "the starting material must have impurities in it."

And those are the only changes. Those aren't changes, at least from an invalidity standpoint, that are material or in any way different from Claim 9, the scope from -- at least from an invalidity standpoint is we're looking at the exact same treprostinil that's already been invalidated.

And so that's why, in a case where there's no patentable distinction, this regulation is, I think, intended to ensure that there isn't an APA violation of the -- by the administrative agency where one side is issuing the same claims in the same week as another side of the agency is invalidating them.

And I think that's why it refers to both patent applicant for applications and

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owners. And I think the agency certainly had the authority to invalidate patents issuing at around the same time based on 316(a)(4), where the Patent Office was given the power to control its proceedings, included in related cases like this. And I think that's where the power for 42.7(d)(3) derived from.

JUDGE HARLOW: Okay. Thank you.

MR. POLLACK: Does that make sense?

JUDGE HARLOW: It does. We understand your position.

Mr. Maebius, would you like to respond?

MR. MAEBIUS: Yes, Your Honor. Let me point out, first of all, that this rule has been interpreted in IPR 2014-00346 where the Panel found that adverse judgment means unappealable final decision; and that's at Paper No. 32, pages 8 to 9.

And so this specific language is different from the term "final written decision." This rule refers to an adverse

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judgment. And another Panel in the same IPR ruled that it only refers to an unappealable final decision.

And part of the reason they held that way is because they noted the statutory language of Section 318(b), which says, if the Patent Trial and Appeal Board issued a final written decision under Subsection A and the time for appeal has expired or any appeal has terminated, then the director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable.

So for all the reasons you mentioned earlier, we agree that this decision is not yet an unappealable final decision, so the rule shouldn't have effect for that reason.

And in addition to that, as you pointed out, it applies to taking action after an adverse judgment. So even if you put aside this first issue, it can't have applied to the continuations which, as you

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pointed out, have distinct claim language.

And in addition to that, they also have evidence and arguments that were presented in the file history that weren't a part of the IPR file. So there's also further reasons why the examiner's decision in those cases is not inconsistent with the later decision.

But we don't even think the rule would apply at all, because the final written decision hadn't come out at the time the examiner made these decisions.

MR. POLLACK: Can I respond to that, Your Honor?

JUDGE HARLOW: Briefly, please.

MR. POLLACK: Yes, okay.

MR. POLLACK: In regard to the Panel decision that Mr. Maebius referred to -- and I recognize that those decisions [sic] made the statements that he described, the Patent Office itself, in promulgating this Rule 42.7(d)(3), in its notice and comment for the rule final, and that can be found at 77 Federal Register 46112 at page

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