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P R O C E E D I N G S

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICROBIOTICA, LIMITED,

Petitioner,

v.

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM,

Patent Owner.

PGR2023-00026

Patent 11,395,838

Transcript of Teleconference Meeting
Conducted on September 14, 2023

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TELECONFERENCE MEETING
CONDUCTED TELEPHONICALLY
Thursday, September 14, 2023
3:30 p.m. EST

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Reported by: Pamela L. Beck

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A P P E A R A N C E S

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JUDGE JEFFREY FREZMAN

JUDGE JAMIE WISZ

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1 P R O C E E D I N G S

2 JUDGE MITCHELL: We are on the call today
3 because the Petitioner asked for authorization to
4 file a reply brief in the case to address the Amgen
5 case that has come down from the Supreme Court. And
6 also to address opinions and exhibits that are
7 raised in the expert declaration filed by the Patent
8 Owner. And with that, I will ask Mr. Kroon if you
9 would start us off, why you think we should give you
10 this authorization.

11 MR. KROON: Sure. Thank you, Your Honor.
12 This is Christopher Kroon, again, from Duane Morris
13 on behalf of Petitioner. So as the Court is aware,
14 the Petitioner filed its petition on April 26th,
15 2023. And the petition challenges all claims of the
16 patent on two primary grounds. First, we raised
17 three counts under section 112 for lack of written
18 description, lack of enablement and indefiniteness.
19 And second, there are two counts of obviousness
20 under section 103.

21 On August 22nd, '23, Patent Owner filed a
22 73-page preliminary response and a 75-page expert

1 declaration. And in that response, Patent Owner
2 raised several arguments that we believe Petitioner
3 could not have anticipated, and for which we believe
4 good cause exists to allow Petitioner to briefly
5 address by way of a short response.

6 As you noted, the first issue is of
7 course the Supreme Court's intervening decision in
8 Amgen. The Amgen decision was issued on May 18th,
9 2023 after the petition was filed but before Patent
10 Owner's preliminary statement was filed. We believe
11 that decision is highly material to the issues of
12 enablement presented in the petition, and it was not
13 addressed in any way in Patent Owner's response.

14 As the Board is I'm sure aware, in Amgen,
15 the Supreme Court found that claims directed to an
16 entire genus of antibodies that performed a desired
17 function were invalid, because although the patent
18 disclosed 26 exemplary antibodies, the claims read
19 on potentially millions of antibodies that were not
20 taught. The Court held that, you know, if the
21 patent claims an entire class of subject matters,
22 that the specification must enable a person skilled

1 in the art to make and use the entire class of
2 subject matter. In other words, the more one
3 claims, the more one must enable.

4 And we believe that the issues before the
5 Amgen court are the same issues raised in our
6 petition. Like in Amgen, the Patent Owner in this
7 case seeks to monopolize every method of
8 administering a composition that contains at least
9 some Ruminococcus bacteria defined by desired
10 outcome in reducing or delaying the growth of a skin
11 cancer tumor. There are thousands of Ruminococcus
12 bacteria, and millions, if not hundreds of millions,
13 of combinations of such bacteria that could be
14 present. And like Amgen, Patent Owner here has
15 failed to disclose an equality running through the
16 claim method that provides a peculiar fitness for a
17 particular purpose, and the scope of the claims is
18 not discoverable through any sort of reasonable
19 experimentations.

20 Now, we suspect that Patent Owner has a
21 different view of the impact of that decision, and
22 it's for that reason we feel that some discussion of

1 the Court's decision in Amgen will benefit the Board
2 in evaluating whether to institute PGR in this case.
3 I'm happy to pause there or continue on to the other
4 grounds, however the Court would prefer to hear
5 argument.

6 JUDGE MITCHELL: Yes, let's pause there
7 and let me hear from Patent Owner on that issue, on
8 the Amgen issue.

9 MS. ELLISON: Thank you, Your Honor.
10 There are both procedural and substantive reasons
11 for denying Petitioner's request here and for why
12 their request lacks good cause. First, their
13 request is untimely. The Amgen decision came out
14 four months ago before the POPR was filed. So if
15 they thought that the Amgen decision impacted the
16 arguments in the petition, they should have sought
17 authorization right away to brief the issue before
18 the POPR was due. But instead, they waited until
19 three weeks after the POPR was filed.

20 Second, procedurally -- actually, let me
21 say this. Certainly Petitioner was aware of the
22 Amgen case, because both the Supreme Court case and

1 a 2019 Federal Circuit decision that the Supreme
2 Court affirmed were widely discussed amongst the
3 Patent Owner. And even just one day after the
4 Supreme Court decision came out, Mr. Kowalski, who
5 is backup counsel here, filed an alert on his law
6 firm's website, or published an alert on his law
7 firm's website talking about the petition. So
8 there's not good cause that the Petitioner has
9 rested on.

10 And secondly, substantively there's also
11 not good cause. And the POPR did not create good
12 cause here. As Mr. Kroon mentioned, the POPR never
13 even mentioned the Amgen v Sanofi Supreme Court
14 case, and that's because neither the petition -- the
15 petition never mentioned the Federal Circuit case.
16 The Federal Circuit case came out in 2019. The
17 supreme Court case affirmed that, and so neither
18 party has discussed the Federal Circuit's decision
19 that the Supreme Court affirmed. So there's no good
20 reason and no good cause to brief the Supreme
21 Court's affirmance of a case that neither party has
22 cited.

1 Moreover, the Supreme Court case did not
2 change the law when it affirmed the Federal
3 Circuit's 2019 decision. Even the Supreme Court
4 stated at page 19 of this decision that it was
5 simply 150 year old law. They said for more than
6 150 years, this Court has been forced the statutory
7 legal requirement according to its terms. Today's
8 case may involve a new technology, but the legal
9 principal is the same.

10 So if Petitioner wanted to make arguments
11 based on the legal principles that were laid out in
12 the Amgen v Sanofi case, they should have relied
13 upon on the 2019 Federal Circuit case that the
14 Supreme Court affirmed, or they could have relied on
15 the same 150 year old case law that the Supreme
16 Court cited in its decision. But they didn't
17 mention any of that case law, Your Honor. Instead,
18 their enablement argument, which appears on page 47
19 of their petition, was only four sentences long and
20 it cited only in re Wright case.

21 So it appears here that the Petitioner
22 wants to make new arguments that they could have

1 made when they filed their petition, given that all
2 of that law is old case law. So this is not a
3 situation where they couldn't have anticipated
4 Supreme Court or any other Court's application of
5 Amgen v Sanofi. They could have made this argument
6 in their petition, Your Honor. Their request is
7 untimely and substantively unnecessary.

8 JUDGE MITCHELL: Let me ask you this. Is
9 it your view that in making our petition on whether
10 or not to institute this review, that we do not need
11 to address the Amgen case?

12 MS. ELLISON: That's correct, Your Honor.
13 Neither party addressed this case, and so there's no
14 need for the additional briefing that Petitioner
15 asked for here. And since neither party has
16 addressed the Supreme Court case or the prior
17 Federal Circuit case, which went -- you know, the
18 law went unchanged on that issue. So neither party
19 addressed that in their briefs. I don't see a need
20 for the Board to address that case.

21 But I think what's even more important on
22 this issue here, Your Honor, is here the Petitioner

1 sends an entirety of four sentences at page 47 of
2 their petition addressing enablement. And now
3 they're asking for a lengthy reply, plus a
4 declaration to address issues that they could have
5 and should have, if they wanted to, raise in their
6 petition. It's untimely and substantively
7 unnecessary.

8 MR. KROON: Your Honor, if I could
9 address that for a minute.

10 JUDGE MITCHELL: Yes.

11 MR. KROON: I mean, I think it's
12 unquestionable that the Board would need to address
13 the Amgen decision and its decision to institute. I
14 mean, it is controlling law issued from the Supreme
15 Court that postdate the filing of our petition. And
16 certainly Patent Owner's arguments here run contrary
17 to the Court's decision in that case. So I think
18 this is absolutely an issue that the Board needs to
19 address and would benefit from the briefing.

20 As I mentioned before, clearly the
21 parties disagree as to its applicability to the
22 facts in this case, and that's where the Board would

1 benefit from understanding those positions and how
2 it might apply. And, again, this is not an instance
3 where we're seeking a lengthy briefing or a
4 protractive briefing schedule. We just are seeking
5 a short opportunity to present cogent arguments to
6 the Board to help it with its decision.

7 MS. ELLISON: Your Honor, if I may --

8 JUDGE MITCHELL: Just one minute, and I
9 will certainly -- you can express what you would
10 like. But let me ask, Mr. Kroon, why the delay?
11 When the case came down, if you thought it was
12 applicable, why did you not ask before now to
13 address it?

14 MR. KROON: Well, respectfully, Your
15 Honor, I don't think there has been really any
16 delay. I mean, we anticipate that Patent Owner
17 would certainly address it in their reply. They
18 didn't do that. And it's not clear how or why they
19 wouldn't do that. And so this -- and I think we've
20 been fairly responsive here in seeking leave from
21 the Board to file this reply. And given the timing
22 of the Board's decision, it certainly wouldn't

1 impact the timing of when that decision would be
2 issued within the statute of confines.

3 JUDGE MITCHELL: Okay. Thank you. And
4 now Ms. Ellison.

5 MS. ELLISON: So of course there's no
6 argument that a Supreme Court case is controlling
7 law. But the issue is, is it relevant to any
8 argument that the Petitioner put in their petition?
9 And the answer is no. Your Honor, they could have
10 argued the Federal Circuit version of the Amgen v
11 Sanofi case, but they did not, and that's why it's
12 not addressed in our POPR. So neither party has
13 argued about this case, and so it's not an issue in
14 this case.

15 And of course the Board's role, I believe
16 you would agree, I hope you would agree, is to
17 adjudicate the issues that the parties have --
18 adjudicate the issues that the parties have
19 presented based on what's in the petition. The
20 petition did not address arguments under Amgen v
21 Sanofi. So what the Petitioner is asking for now is
22 really a chance to redo their arguments, a chance

1 for a second bite at the apple, and that is not what
2 replies are for. There's no good cause for that,
3 Your Honor.

4 They could have addressed the Amgen v
5 Sanofi or the 150 year old case law that Amgen
6 cites, and they chose not to do either. That was
7 their strategic failure to make only a four-sentence
8 argument in their petition. And their request is
9 untimely, Your Honor. They knew about this case.
10 They published on it the day after the Supreme Court
11 decision came out. I think any patent attorney
12 worth their salt knew about the Amgen v Sanofi case
13 when it came out, and yet they waited until four
14 months after that decision, they waited until after
15 the POPR was filed. There's no reason to expend
16 additional resources and the Board's energy and time
17 on this issue.

18 MR. KROON: And --

19 JUDGE MITCHELL: Thank you. Go ahead.

20 MR. KROON: With respect to the length of
21 any arguments addressed in the petition, we
22 certainly have a very extensive discussion in the

1 petition of section 112 that deals with highly
2 overlapping issues between written description and
3 enablement. The fact that counsel would assert that
4 any attorney worth their salt would be aware of this
5 decision is proof in and of itself that this is a
6 decision that the Board can't -- that the Board must
7 address in its decision to institute. And having
8 the benefit of some briefing and how the parties
9 view the application of that decision to the facts
10 of this case can only benefit the Board.

11 MS. ELLISON: It just goes to show, Your
12 Honor, that they're trying to make the arguments
13 that they've not made in their petition. They're
14 seeking an opportunity to do that, and they should
15 be denied that argument. They could have addressed
16 the Amgen v Sanofi and some other case law,
17 including 150 year old case law in their petition,
18 but they chose not to. And they should not be given
19 a chance to make up now for their strategic choices.

20 JUDGE MITCHELL: Thank you both. I think
21 we understand the first dispute. So let's move to
22 the second issue raised by Petitioner, where

1 Petitioner is seeking an opportunity to address the
2 opinions and exhibits waived in the declaration
3 submitted by the Patent Owner. Mr. Kroon.

4 MR. KROON: Thank you, Your Honor. And
5 so the second grounds for good cause relates to, I
6 think, two categories of art relied upon by Patent
7 Owner's expert. The first category relates to
8 post-filing enablement art. In opposition to
9 Petitioner's enablement argument, Patent Owner's
10 expert relies on several references that postdate
11 the filing of the patent.

12 Having reviewed that art, we clearly
13 disagree with how it was applied by Patent Owner.
14 And, again, here's a situation where Patent Owner
15 could not have anticipated that -- or Petitioner,
16 excuse me, could not have anticipated that Patent
17 Owner would rely upon post-filing art, and certainly
18 not the specific art they relied upon.

19 Now, I'll be happy to get into more
20 detail. But as the Board I'm sure is aware,
21 post-filing art may sometimes be admissible to prove
22 the state of the art at the time of the filing, but

1 there are rules with respect to its application.
2 Post-filing art cannot be used to add knowledge of
3 the art after a patent application is filed. The
4 data in post-filing art must be commensurate in
5 scope with that disclosed in the application. And
6 in order to establish enablement, of course it still
7 must enable the full scope of the claims as made
8 clear no less by the Amgen decision.

9 Now, we believe that the post-filing art
10 relied upon by Patent Owner's expert can't meet any
11 of these requirements. And, again, seek leave to
12 allow our expert to briefly opine on the art relied
13 on by Patent Owner's expert. Now, the second --

14 JUDGE MITCHELL: I want to ask you on
15 timing since, you know, we're in this preliminary
16 stage. We have -- I guess we're a little over two
17 months out from the time when we have to issue our
18 decision. And I'm always a little, you know,
19 worried that can that timing work when you're
20 bringing a second declaration at the preliminary
21 stage. Tell me how that timing would work.

22 MR. KROON: Sure. Thank you, Your Honor.

1 We can be very quick on getting a declaration. It
2 would not be a lengthy declaration by any stretch.
3 It would simply address the two -- I believe there's
4 two post-filing enablement references. I think
5 within a week we can have it before the Board.

6 JUDGE MITCHELL: Okay. Thank you.

7 MR. KROON: And there's a second category
8 of art. Again, I'm happy to take them one at a time
9 if that's helpful or address it right now.

10 JUDGE MITCHELL: Sure, go ahead. You can
11 go ahead and address it now.

12 MR. KROON: Okay. Thank you. So the
13 second category of art relates to a reference that
14 Patent Owner contends it's cumulative of one of
15 Petitioner's primary references. And specifically
16 Patent Owner contends that the Tokyo reference is
17 cumulative of the Honda reference relied upon by
18 Petitioner in its 103 combination.

19 Now, we believe that Patent Owner has
20 mischaracterized Tokyo's relation to Honda. In
21 particular, the Tokyo reference has a nearly
22 three-year earlier filing date than Honda. And

1 Honda does not claim priority to Tokyo, and their
2 specifications do not overlap. So we think they're
3 not related in that sense. And in addition, the
4 disclosure in Honda that Petitioner relies upon is
5 the claims. And the claims, the disclosure in the
6 claims, they were issued after the Tokyo reference
7 was issued. So those claims could not have been
8 before the examiner during prosecution.

9 Again, the Petitioner couldn't have
10 anticipated that Patent Owner would rely upon Tokyo,
11 and believes that the Board would benefit from
12 additional briefing on these points in connection
13 with its institution proceeding.

14 JUDGE MITCHELL: Thank you. Ms. Ellison,
15 your response.

16 MS. ELLISON: Thank you, Your Honor.
17 Once again, there is not good cause to support the
18 Petitioner's requests here. First, regarding
19 post-filing date art and discussing art, I'll note
20 that Petitioner's expert, Dr. Robinson, in the
21 context of addressing brief description and
22 enablement, he didn't discuss the art at all. So

1 his abject failure to consider art, which of course
2 is a key consideration, his abject failure to do
3 that does not somehow create good cause for a reply,
4 and that includes post-filing date art.

5 The post-filing date art that we relied
6 upon are Exhibits 2019 and 2020, both of which were
7 published in the year 2021. These exhibits were
8 published -- or these papers were published in the
9 Journal of Science, which is widely recognized as
10 one of the most prestigious and influential journals
11 around. So certainly an expert who has done any
12 kind of diligent assessment of the art would have
13 been aware of these references and should have --
14 and Dr. Robinson should have considered those in
15 support of the petition since, as even Mr. Kroon
16 acknowledges, post-filing date art can be relevant
17 to the issue of enablement. So again, just because
18 the Petitioner has done a cursory job in their
19 petition and in providing their expert declaration,
20 this does not create good cause for them to seek a
21 reply.

22 Now, regarding the Tokyo reference. The

1 Tokyo reference comes up in the context of 325(d).
2 And Dr. Garrett, our expert, addressed the Tokyo
3 reference. And she demonstrated how the Tokyo
4 reference raises substantially the same, the same or
5 substantially the same issues as the Honda reference
6 that the Petitioner used as their primary reference
7 in the petition.

8 So I think we are all aware that under
9 325(d) in Advanced Bionics, the burden is on the
10 Petitioner to explain why the art that's relied on
11 in their petition did not raise the same or
12 substantially the same arguments that were raised
13 during prosecution. Certainly the Petitioner here
14 knew about that, because they mentioned the Advanced
15 Bionics case in their petition. But, again, their
16 analysis of Advanced Bionics is very cursory. They
17 made no effort to explain how the Honda reference is
18 not cumulative to the Tokyo reference that we cited.

19 But what's particularly astonishing about
20 their failure to do that, Your Honor, is the Tokyo
21 reference, it wasn't just a random reference cited
22 in an IDS. The Tokyo referenced was cited in the

1 International Search Report as being a document of
2 particular relevance. And also, it was cited in the
3 written opinion from the International Searching
4 Authority. And it was cited as allegedly
5 establishing a lack of novelty over then pending
6 Claim 44. So the Tokyo reference was front and
7 center in prosecution, and yet the applicants -- the
8 Patent Owner overcame this reference.

9 And finally, I'll also note that it's not
10 unforeseeable or unexpected that the Patent Owner
11 would raise issues regarding the Tokyo reference,
12 when all of the inventors who were on the face of
13 the Honda reference that Petitioner uses as its
14 primary reference, all those inventors are also
15 inventors on the face of the Tokyo reference. So
16 it's entirely foreseeable that the Patent Owner and
17 our expert would have addressed the relevance and
18 the cumulativeness of Tokyo, the relevance of that
19 as compared with the Honda reference cited in the
20 petition.

21 So, once again, Petitioner's strategic
22 choice not to compare the Honda reference to any

1 art, including the Tokyo reference that was front
2 and center, and Petitioner's strategic choice to do
3 only a very cursory Advanced Bionics analysis does
4 not create good cause for a reply.

5 MR. KROON: Your Honor, if I may.

6 JUDGE MITCHELL: Sure.

7 MR. KROON: Petitioner does not have a
8 crystal ball. We would have no reason to anticipate
9 that Patent Owner would rely on any of these
10 references given that none of them are relevant to
11 the issues in this case. And I explained --
12 originally the post-filing art, it is neither
13 commensurate in scope with the data disclosed in the
14 patent, nor does it enable or come close to enabling
15 the scope of the claims. So there's no reason why
16 our expert would ever anticipate evaluating the
17 post-filing art relied upon by Patent Owner.

18 And with respect to Tokyo, again, there
19 is -- the disclosure in Honda on which we rely is
20 the claims. The claims are not disclosed in the
21 Tokyo reference, and the subject matter of the
22 claims is not disclosed in the Tokyo reference. So,

1 again, our expert would have no reason to opine on
2 Tokyo, nor would Petitioner.

3 So, you know, all of these reasons,
4 frankly, and the disagreement between Patent Owner
5 and Petitioner as to the impact of these references,
6 I think supports the good cause for why some
7 additional briefing on the issue would benefit the
8 Court, the Board in determining whether to institute
9 this or not.

10 MS. ELLISON: Your Honor, if I may --

11 JUDGE MITCHELL: Let me ask this one
12 quick question, and then certainly I'll let you say
13 what you would like, Ms. Ellison.

14 Mr. Kroon, for your expert facts that
15 you're proposing to file, would your expert witness
16 only address the post-filing enablement art or also
17 the cumulative nature of Tokyo and Honda?

18 MR. KROON: I think the intent would be
19 to address all three references. But, again, I
20 think that can be done fairly succinctly and
21 expeditiously.

22 JUDGE MITCHELL: Okay. Thank you. Now

1 Ms. Ellison.

2 MS. ELLISON: Your Honor, it's quite
3 astonishing that Petitioner's counsel would say that
4 they had no reason to anticipate that Patent Owner
5 would discuss the Tokyo reference, when the Tokyo
6 reference was cited during prosecution and it has a
7 reference in the International Searching Authority's
8 International Search Report as being document,
9 quote/unquote, document of particular relevance, and
10 when it was used for lack of novelty assertion
11 during prosecution, this was about as foreseeable as
12 it gets. So it's astonishing that Petitioner would
13 assert lack of foreseeability here.

14 Second, regarding the particular
15 post-filing date part that Patent Owner cited, one
16 of the references is a publication by the inventor
17 of the patent that Petitioner challenged. Again,
18 published in the Journal of Science, which patent
19 owner's expert, Dr. Garrett, cites the publication
20 in her declaration, Exhibit 2025 I believe it is,
21 which is an independent third-party publication
22 explaining to the world that Science -- the Journal

1 of Science is one of the most influential and
2 prestigious journals around.

3 So Dr. Robinson, Petitioner's expert, who
4 is supposedly an expert in this area and who works
5 for a company in this exact state, certainly if he's
6 done any degree of diligence, would have found -- or
7 a POSA doing any degree of diligence could have been
8 aware of or would have been aware of post-filing
9 date art that is squarely on point as the two
10 references that we cited. But, again, Petitioner
11 chose to do a cursory analysis of the 325(d) issues
12 in their petition.

13 And then finally, I'd like to say if for
14 some reason the Board were to find somehow that
15 there's good cause here and allows Petitioner to
16 submit a reply, the Board should not allow a further
17 declaration. Doing so would be highly unusual.
18 Certainly Petitioner has cited no precedent for
19 allowing a further declaration at this point in
20 time. And if Petitioner were to have the
21 opportunity to file a further declaration, certainly
22 due process requires Patent Owner to be able to file

1 a further declaration.

2 And I'll say that it would take us -- we
3 would need multiple weeks to be able to pull that
4 together. One, to be able to retain an expert who
5 can address the Petitioner's additional expert
6 declaration and digest it and prepare an appropriate
7 reply. And I think that would create unnecessary
8 strain on and expense for both the Patent Owner and
9 for the PTAB all because the Petitioner did a very
10 cursory analysis in presenting their petition.

11 That's not good cause, Your Honor. Their abject
12 failure to address these issues that would have been
13 well known and anticipated by anyone doing any
14 degree of diligence does not create good cause that
15 more is subjecting Patent Owner and the PTAB to this
16 additional work. So thank you, Your Honor.

17 JUDGE MITCHELL: Thank you. Let me ask
18 you, Ms. Ellison, and I absolutely agree that the
19 Patent Owner gets the last word, and you could
20 certainly have the opportunity to respond to that.

21 Are you telling me that your experts that
22 you have now may or may not be available to respond

1 to a declaration should we allow Petitioner to put
2 in a supplemental declaration at this time?

3 MS. ELLISON: I don't know whether our
4 expert that we have now could submit a response if
5 you were to allow Patent Owner to submit a
6 declaration. Certainly, you know, when we retained
7 our expert, we were well aware of the deadline for
8 submitting a POPR and for submitting her supporting
9 testimony. But to allow a further declaration from
10 Petitioner in this stage would be highly unusual, so
11 I cannot confirm that we would be able to have an
12 expert available. I'll also note that our expert is
13 a practicing clinician at Harvard, and of course has
14 a very busy schedule, and so to try to impose upon
15 our expert additional unforeseen -- this is
16 unforeseen, additional unforeseen work at this point
17 with any kind of tight deadline, I cannot confirm
18 that that would be doable.

19 And just one last thing, which is, there
20 aren't a million of these experts out there, Your
21 Honor. So it's not as though we could easily go
22 find an expert in a day or two. That's not a simple

1 task. There are very few experts in this field.
2 Petitioner used one of their own employees, which I
3 think probably reflects what I just said to you,
4 which is that it's not a simple matter to just
5 retain an expert in this field.

6 So if Petitioner is allowed to submit an
7 expert, a further expert declaration at this point,
8 we certainly would want to submit one, but I cannot
9 confirm that we would be able to do that with the
10 expert of our choice any time soon. And, again,
11 this would be prejudicial to the Patent Owner, and
12 it's all an issue of Petitioner's own making for
13 having done such a cursory analysis in the first
14 place.

15 MR. KROON: Your Honor, if I may?

16 JUDGE MITCHELL: Go ahead.

17 MR. KROON: Thank you. Putting aside the
18 repeated ad hominem attacks as to Petitioner, you
19 know, we certainly agree that Patent Owner should
20 have the opportunity to file its own response to our
21 reply should one be allowed. You know, I didn't
22 hear from counsel that their expert is not

1 available. They simply haven't confirmed with their
2 expert whether she is available. You know, I'll
3 note she's getting paid \$750 an hour, so presumably
4 she would make herself available, as most of our
5 experts do in these cases that I'm sure you've seen
6 in past experience.

7 Now, they used an expert to opine on art,
8 we believe we should be permitted to respond in
9 kind. But I'll add that to the extent that the
10 Board wants only attorney argument or just attorney
11 briefing on these issues that we've identified, you
12 know, if that is to quell the concerns from Patent
13 Owner, we can move forward on that basis as well.
14 But I think the importance here is that the Board
15 gets the benefit of additional understanding related
16 to the Amgen decision and the three references here
17 that we've identified.

18 JUDGE MITCHELL: All right. Thank you
19 for that. I think we understand the second issue.
20 So let me go on a brief hiatus on the call and
21 confer with the Panel, and I will be right back.
22 Thank you.

1 MR. KROON: Thank you very much.

2 (Panel confers.)

3 JUDGE MITCHELL: This is Judge Mitchell
4 back on the line. We have conferred, and thank you
5 for that because I think it was very helpful in
6 flushing out what we heard from both sides here. We
7 do think that additional briefings from both sides
8 might be helpful on the issues that were raised by
9 Petitioners. But the declarations may not be at
10 this point as helpful with the timing issues that we
11 would have to get this decision out by
12 November 22nd.

13 So at this point we would like to
14 authorize additional briefing on the issues by both
15 parties, but no additional expert declaration at
16 this preliminary stage. I didn't get a -- I should
17 have asked Petitioner what you had in mind for page
18 length for the --

19 MR. KROON: Yes. Your Honor, sorry, I
20 should have mentioned that myself. So I think what
21 we would like to seek the Board's permission is to
22 file a ten-page reply.

1 JUDGE MITCHELL: Okay. And that's
2 something you can prepare in a week?

3 MR. KROON: Yeah, I think we can do that.

4 JUDGE MITCHELL: Or that's fine if you
5 would like a little more time.

6 MR. KROON: Could we ask for ten days,
7 and then if we can get it in a week, do so.

8 JUDGE MITCHELL: Certainly.

9 MR. KROON: Okay. That would be
10 appreciated. Thank you.

11 JUDGE MITCHELL: So ten business days is
12 what you're asking?

13 MR. KROON: If possible, yes, that would
14 be terrific.

15 JUDGE MITCHELL: Okay. Great. And now
16 Ms. Ellison.

17 MS. ELLISON: Well, Your Honor, I'd like
18 to clarify the question firstly. When you're
19 saying --

20 JUDGE MITCHELL: This is the -- oh, go
21 ahead if you have a question for me.

22 MS. ELLISON: The question is just

1 clarifying the scope of the briefing. Is it limited
2 to the Amgen decision and the two post-filing date
3 references and the Tokyo reference?

4 JUDGE MITCHELL: Yes.

5 MS. ELLISON: Okay. Thank you for
6 clarifying that.

7 JUDGE MITCHELL: Yes, limited to the
8 issues Petitioner raised, yes.

9 MS. ELLISON: Okay. I was just asking
10 because Petitioner's email to us was far reaching in
11 terms of the scope, so I just wanted to make sure
12 it's clear that the briefing is limited to those
13 three references to the Amgen decision.

14 JUDGE MITCHELL: Yes. And I will issue a
15 short order to make that clear for the record. But
16 would ten business days be doable for you to
17 respond?

18 MS. ELLISON: Well, I would actually
19 request 20 business days from today since you're
20 giving Petitioner ten business days to submit their
21 brief, and then I would like an additional ten
22 business days. Since they may submit theirs

1 earlier, I need that full time from today, 20
2 business days.

3 JUDGE MITCHELL: Okay. That is fair. I
4 will give you at least the full ten business days.
5 So I will --

6 MS. ELLISON: And I actually -- sorry,
7 Your Honor. Just because it's unclear when
8 Petitioner will submit their brief, I was asking for
9 20 business days from today as opposed to ten
10 business days from whatever indeterminate time they
11 submit their brief so that I can plan my schedule
12 and docket around that.

13 JUDGE MITCHELL: I understand, and I
14 think that hard date is in the order.

15 MS. ELLISON: Thank you, Your Honor.

16 JUDGE MITCHELL: Is there anything else
17 from the Petitioner that we need to discuss?

18 MR. KROON: Not at this time, Your Honor.
19 Thank you.

20 JUDGE MITCHELL: And anything from Patent
21 Owner?

22 MS. ELLISON: I mean, I'll just note,

1 Your Honor, that ten pages seems impressive here.
2 And also, just to be clear, I take it you're not
3 authorizing Petitioner to make a brand-new set of
4 legal series and arguments beyond what the petition
5 itself says, correct, Your Honor?

6 JUDGE MITCHELL: Well, I'm authorizing
7 them to be able to address the Amgen case, which is
8 not raised in the petition, or as I understand that
9 the Patent Owner responds on the other two issues.
10 So limited exclusively to the issues raised in the
11 email that we got from Petitioner and what we
12 discussed today.

13 MS. ELLISON: But even in applying the
14 Amgen case, they should be limited to the legal
15 series of arguments that were presented in the
16 petition as opposed to making a whole new set of
17 arguments that were never previously presented given
18 that the 2019 Amgen case existed and was merely
19 affirmed by the Supreme Court.

20 JUDGE MITCHELL: Well, certainly,
21 Ms. Ellison, you can point that out in your briefing
22 if you think Petitioner has gone beyond the scope of

1 the petition.

2 MS. ELLISON: Thank you, Your Honor.

3 Okay. So, again, I'll submit respectfully that ten
4 pages is more than what is typically given when a
5 Petitioner requests a reply. I think it's excessive
6 here, with all due with respect. But as long as you
7 give us an equal page length, obviously we will
8 respect whatever decision you come to on that point,
9 Your Honor.

10 JUDGE MITCHELL: Thank you, and I
11 certainly would give an estimate for the amount of
12 pages. And I do think ten pages allows you ample
13 room to say what needs to be said. I always like to
14 make sure you have to enough to say what you need
15 to. Because certainly you know your case better
16 than I do, and I always want to hear what you have
17 to say and not necessarily restrict your ability to
18 express what you need to say.

19 I'd rather give you a little more than
20 have too little, and you don't get to tell me
21 exactly what you need to say about the case. I
22 might give a little bit much, but I would rather

1 have more than less from both parties to really be
2 able to express the issues and for me to make sure
3 that I'm hearing everything that you need to say for
4 your case.

5 MS. ELLISON: Thank you for the
6 clarification, Your Honor, and thank you for
7 considering our position today. We very much
8 appreciate it.

9 JUDGE MITCHELL: Sure, yes, of course.
10 Well, if there's nothing else, and let me ask the
11 court reporter, did you have anything that you
12 needed to ask me before we adjourn the call,
13 anything you didn't hear or understand in the
14 wording?

15 THE REPORTER: No, Your Honor.

16 JUDGE MITCHELL: Usually when we have a
17 court reporter, we prefer to have the transcript
18 entered into the record. But if both parties agree
19 that they don't want that, that is fine with me.
20 But I would want to make sure both parties agree
21 that we're not going to enter any transcript into
22 the record.

1 MR. KROON: Your Honor, I think we're
2 okay if it's filed in the record for Petitioners.

3 MS. ELLISON: Your Honor, the Patent
4 Owners requested the court reporter, so we're fine
5 submitting the transcript into the record, and we'll
6 do so.

7 JUDGE MITCHELL: Okay, great. Well,
8 thank you. If there is nothing else, this call is
9 adjourned. Thank you so much.

10 MR. KROON: Thank you, Your Honor.

11 MS. ELLISON: Thank you.

12 (Off the record at 4:22 p.m.)
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1 CERTIFICATE OF COURT REPORTER - NOTARY PUBLIC

2
3 I, Pamela L. Beck, the officer before whom the
4 foregoing proceedings were taken, do hereby certify
5 that the foregoing transcript is a true and correct
6 record of the proceedings; that said proceedings
7 were taken by me stenographically, and thereafter
8 reduced to typewriting under my supervision; and
9 that I am neither counsel for, related to, nor
10 employed by any of the parties to this case, and
11 have no interest, financial or otherwise, in its
12 outcome.

13 IN WITNESS WHEREOF, I have hereunto set my hand
14 and affixed my notarial seal this 18th day of
15 September.

16
17
18 My commission expires January 14, 2027.

19 *Pamela L Beck*
20 _____

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