

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01136
Patent 8,399,514 B2

Before FRED E. McKELVEY, SALLY GARDNER LANE, and
DEBORAH KATZ, *Administrative Patent Judges*.

McKELVEY, *Administrative Patent Judge*.

DECISION
Denying Request for Rehearing
37 C.F.R. § 42.71(d)(2)

I. Introduction

Petitioner timely filed a Request for Rehearing under 37 C.F.R. § 42.71(d)(2) (Paper 26) seeking reconsideration of our decision declining to institute an IPR trial (Paper 23 “Decision”).

Patent Owner was invited to file an opposition. Paper 27.

Biogen’s Opposition to Request for Rehearing was thereafter timely filed. Paper 28.

For the reasons given below, the Request for Rehearing is *denied*.

The analysis set out below is based in large measure on arguments as presented in the Opposition.

II. Kappos 2005

1. On page 2, line 19 – page 3, line 15 of the Request, Petitioner states that the Decision declining to institute an *inter partes* review and order a trial overlooked or misapprehended that Kappos 2005 is a § 102(b) printed publication. The Decision does not question the prior-art printed publication status of Kappos 2005.

2. On page 3, lines 3–6, Petitioner states that mention of a pilot study by Kappos 2005 did not negate the content of Kappos 2005 or render it less than a printed publication. The Decision did not question the prior-art status of Kappos 2005 or suggest that the pilot study negated the content of Kappos 2005. Rather, we found that the pilot study was not of record. Decision, page 9.

3. On page 3, line 16 – page 4, line 14, Petitioner states that the Decision overlooked or misapprehended Dr. Linberg’s phrase “appears to be” in paragraph 27 of his declaration (**Ex. 1005A**). We discussed “appears

to be” on page 9 of the Decision. We gave more weight to pre-litigation statement by Kappos than to post-litigation conclusory expert testimony. *See Velandier v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (holding that Board did not abuse its discretion in giving more weight to documentary evidence vis-à-vis witness testimony). Furthermore, as Patent Owner points out, the word “appear” is also synonymous with “seem” (<http://www.merriam-webster.com/dictionary/appear>), and is consistent with our statement that what counts is what is described, not what appears or seems to have been tested. Decision, page 9.

4. On page 4, line 15 – page 5, line 2, Petitioner states that the Decision misapprehended or overlooked Dr. Linberg’s statement that the Kappos 2005 dose-ranging study would not have been undertaken unless BG00012 had been determined to be therapeutically active in treating patients with MS and that the Decision cites no *substantial* evidence for interpreting Kappos in a fundamentally different way. The reference to “substantial evidence” is curious since “substantial evidence” is an appellate standard of review for fact finding. The argument should have been that our finding was not supported by a preponderance of the evidence. In any event, Petitioner, in effect, attempts to reargue a case it attempted to make out in the petition and fails to point out how we misunderstood Dr. Linberg’s testimony. Petitioner failed to explain adequately in the Petition why one of ordinary skill in the art, based on Kappos, would have understood that DMF was useful for treating multiple sclerosis (MS).

5. On page 5, lines 3–14, Petitioner states that the Decision misapprehended or overlooked that Kappos 2005 was not guessing, but

stating a fact, i.e., that DMF had been determined to be effective, which is why there would have been a reasonable expectation of success. The argument concerning reasonable expectation of success, as pointed out by Patent Owner in the opposition, is new and therefore could not have been overlooked. *Keebler Co. v. Murray Bakery Products*, 866 F.2d 1386, 1388 (Fed. Cir. 1989) (prescience is not a required characteristic of the board and the board need not divine all possible afterthoughts of counsel that might be asserted for the first time on appeal). Moreover, in our view Petitioner has not pointed out where there is a clear statement in Kappos 2005 that those skilled in the art knew that DMF was useful in treating MS.

6. On page 5, line 15 – page 6, line 6, Petitioner states that our finding that Kappos’s description of “fumaric acid esters” was insufficient to describe DMF misapprehended or overlooked Dr. Linberg’s testimony that it was known that DMF is therapeutically active for treating RRMS based on Kappos’s disclosure of a Phase II study with BG00012. We disagree because the our finding regarding fumaric acid esters concerned Kappos’s mention of the earlier *pilot study*, not the planned Phase II study. Petitioner has not convinced us that we misapprehended any evidence regarding the pilot study’s use of fumaric acid esters. Paragraph 23 of Dr. Linberg’s declaration (cited by Petitioner) does not explain adequately the basis for his opinion.

7. On page 6, lines 7 – 23, Petitioner states that we misapprehended or overlooked Dr. Linberg’s testimony that one of ordinary skill knew that DMF was therapeutically active for treating RRMS. We disagree because we did not misapprehend or overlook Dr. Linberg’s statement. Rather, after

considering Kappos 2005, we found, on the record before us, that Kappos 2005 did not describe DMF as being useful in treating MS. Decision, page 11. The Request for Rehearing fails to convincingly establish how we abused our discretion in giving more weight to the disclosure of Kappos 2005 vis-à-vis Dr. Linberg's testimony. *Velandar*, 348 F.3d at 1371.

8. On page 7, lines 1 – 4, Petitioner states that for obviousness, all that is required is a reasonable expectation of success. Assuming Petitioner is correct, the reasonable expectation of success argument is new on rehearing. Moreover, a review of the record confirms that Petitioner never established any reasonable expectation of success. A new argument on rehearing could not have been overlooked.

9. On page 7, lines 4 – 9, Petitioner states that the Board misapprehended or overlooked Dr. Linberg's testimony that Kappos 2005 describes a routine step in drug development taken after therapeutic activity has been detected. Paragraph 23 of Dr. Linberg's Declaration (cited by Petitioner) does not state that Kappos 2005 describes a routine step in drug development. Moreover, we are not experts on the routine steps of drug development or FDA protocols and therefore if a petitioner intends to rely on routine steps and/or FDA protocols, the petitioner has to educate us on routine steps and/or FDA protocols in a petition. Upon consideration of the evidence presented to us, we found that Petitioner failed to establish that Kappos 2005 teaches that DMF was known to be useful in treating MS.

10. On page 7, lines 10 – 14, Petitioner states that we misapprehended or overlooked Dr. Linberg's testimony that Kappos 2005's dose-ranging study would not have been undertaken unless BG00012 had

been determined to be therapeutically active in treating patients with MS. We disagree because Petitioner inappropriately attempts to reargue its case and presents new argument about the prior art. We also disagree because we considered Petitioner's arguments and found, on the record before us, that Kappos 2005 did not describe DMF as being useful in treating MS.

11. On page 7, lines 14 – 18, Petitioner states that we abused our discretion in finding that the Petition did not establish that Kappos 2005 teaches that DMF would be useful in treating patients with MS. As pointed out by Patent Owner, the open question—according to Petitioner—was whether the drug could be licensed by the FDA to treat MS patients, not whether DMF works. On the record before us, we found that Kappos 2005 did not teach that DMF was known to be useful in treating MS.

12. On page 7, line 19 – page 8, line 7, Petitioner states that a patent may be secured before conclusion of clinical trials, citing *Eli Lilly v. Teva Pharms. USA, Inc.* 619 F.3d 1329 (Fed Cir. 2010) and MPEP § 2107.03. We can agree with Petitioner that a patent can be granted pre-clinical trials. However, granting a patent pre-clinical trial has not been shown to be relevant in this case, and in any event, is a new argument and thus could not have been overlooked. Moreover, we agree with Patent Owner that the cited case and MPEP section relate to enablement and utility, respectively, not obviousness. See *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (holding that obviousness and enablement inquiries turn on different issues).

13. On page 8, lines 8 – 17, Petitioner states that the Decision misapprehended or overlooked that Kappos 2005 describes ongoing clinical

trials, and therefore it was an abuse of discretion to not find a reasonable expectation of success when DMF was being used. We agree with Patent Owner that the argument represents an inappropriate attempt to reargue the petition. In addition, we did not overlook that a Phase II trial was being conducted. Rather, we found that before its completion and evaluation, on this record one skilled in the art would not necessarily understand based on Kappos 2005 that DMF is useful for treating MS. Decision, page 11.

14. On page 8, line 18 – page 9, line 1, Petitioner states that we substituted our own understanding of Kappos 2005 for that of Dr. Linberg in finding that Kappos did not meet the description requirement of § 102(b). We agree with Patent Owner that we considered Kappos 2005 and weighed it vis-à-vis Dr. Linberg’s testimony and, based on the record before us, accorded more weight to Kappos 2005. *Velandar*, 348 F.3d at 1371.

15. On page 9, lines 1 – 11, Petitioner states that the our finding is not supported by evidence, because success in a pilot study, said to be apparent in the background section of Kappos, is a well-known reason for designing dose-ranging studies. Kappos 2005, when weighed against Dr. Linberg’s testimony, led us to find, based on a preponderance of the evidence, that Petitioner was not likely to succeed on the merits. We also note that the pilot study mentioned by Kappos 2005 is not of record. Moreover, we have not been told where Dr. Linberg testified that success in a pilot study is a well-known reason for designing dose-ranging studies. As noted earlier, we are not experts in dose-ranging studies; even if we were experts, or even knowledgeable on dose-ranging studies, we would base our findings on evidence in the record. *Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d

1437, 1448 (Fed. Cir. 1997) (Mayer, C.J., concurring: I “know” what anodization means from my own undergraduate studies and experiments; the concept is not difficult and I need no further education to grasp it. I happen to have a dictionary in my chambers from the era pertinent here, which would confirm my “knowledge” about anodization. . . . But, I am neither an expert in the field nor one of ordinary skill in the art despite how much I think I “know” about a process I once studied. Nor do my colleagues on this court or on the district court possess such expertise, and even if they did, they would have to defer to the record made in the case.). Furthermore, as Patent Owner points out, weighing and determining credibility of the evidence is the special province of the trier of fact. *See Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 856 (1982).

III. ClinicalTrials

16. On page 10, lines 3 – 4 of the Request, Petitioner states that we overlooked or misapprehended the meaning of the term “pilot study.” But, Petitioner fails to identify how this term was overlooked or misapprehended. Petitioner does not dispute that the pilot study is not of record. Our finding that ClinicalTrials describes a pilot study (not of record) has not been shown to be wrong.

17. On page 10, lines 3 – 4, Petitioner states that we overlooked or misapprehended the ClinicalTrials document. Petitioner identifies no portion of ClinicalTrials that we supposedly misapprehended or overlooked.

18. On page 10, lines 4 – 9, Petitioner states that the Board overlooked Dr. Linberg’s testimony that DMF has therapeutic activity for MS. Paragraph 23 of Dr. Linberg’s declaration (cited by Petitioner) contains

only a general statement with no citation to any portion of ClinicalTrials. *See ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (conclusory, factually unsupported expert testimony is insufficient to establish obviousness); *see also Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (Nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 294 (Fed Cir. 1985) (lack of factual support for expert opinion “may render the testimony of little probative value in a validity determination”).

19. On page 10, lines 9 – 15, Petitioner states that the Board overlooked Dr. Linberg’s testimony or “impermissibly substituted its own expertise for that of Dr. Linberg,” who testified that ClinicalTrials taught that DMF is therapeutically active. Petitioner is inappropriately attempting to reargue its case on rehearing. In addition, Dr. Linberg’s opinion in the cited portion of his declaration (**Ex. 1005A ¶ 23**) is conclusory and unsupported, and therefore not convincing. Moreover, we adhere to our finding that ClinicalTrials does not state that DMF is useful for treating MS.

IV. The Alleged ’514 Patent Admission

20. On page 11, lines 9 – 16 of the Request, Petitioner states that we substituted our own incorrect interpretation of Drugs R&D for the alleged ’514 patent admission without evidence that the two are equivalent. We did not address any equivalency. Rather, we analyzed the alleged admission in the *context* of Drugs R&D. Decision, page 15. Petitioner does not dispute that another cited reference (Schimrigk) is not of record.

21. On page 11, lines 16 – 19, Petitioner states that we overlooked or misapprehended Dr. Linberg’s testimony that the ’514 patent admits that one of ordinary skill in the art would have believed that DMF and MMF were therapeutically active for MS. We disagree. We examined the statement in the specification in light of the Drugs R&D publication and determined that it did not support a finding that DMF was known to be useful for treating MS. Decision, page 15. Further, the petition failed to establish a *prima facie* case of obviousness, or a reasonable likelihood of success under AIA pre-trial standards, based on the alleged ’514 patent admission.

22. On page 12, lines 1 – 2, Petitioner states that we cited no evidence contradicting Dr. Linberg’s opinion about the meaning of the alleged admission. We disagree. Rather, we determined that nothing in the alleged admission or Drugs R&D supported a finding that DMF was useful for treating MS. Decision, page 15.

23. On page 12, lines 3 – 19 and page 13, lines 16 – 19, Petitioner states that our holding that it was still an open question as to whether patent admissions per se can be relevant prior art in an IPR was erroneous, citing *Intri-Plex Technologies, Inc. v. Saint-Gobain Performance Plastics Rencol, Ltd.*, IPR2014-00309 (PTAB 2014) (Paper 83, 19 – 29) (admission may be prior art). The citation of *Intri-Plex* is a side show apart from the main event because in rendering our non-institution decision we considered the “admission” in context with Drugs R&D—which is a printed publication. Petitioner failed to establish a likelihood of success based on the alleged admission in combination with Drugs R&D.

24. On page 13, line 4 – page 14, line 3, Petitioner states we misquoted Drugs R&D by leaving out the word “derivative” and that the drug must be an ester of fumaric acid. We agree with Patent Owner because we considered Petitioner’s arguments in light of Drugs R&D, and found that (1) Phase II study results were not in the record and (2) Petitioner failed to establish that DMF was known to be useful for treating MS (Decision, page 15).

25. On page 14, lines 3 – 6, Petitioner states that our reason for not considering whether the ’514 patent admission was applicable prior art is wrong. We disagree because even finding that the alleged ’514 admission is relevant prior art, the petition still failed to establish a likelihood of success.

26. On page 14, lines 7 – 12, Petitioner states that we overlooked or misapprehended the disclosure in Drugs R&D that Biogen Idec was evaluating “the product” in clinical trials. We did not overlook this statement because the Decision analyzed the relevant disclosure of Drugs R&D, including its mention of a Phase II study in MS. (Decision, page 15); we also found that no Phase II study results were in the record (*id.*).

27. On page 14, lines 13 – 20, Petitioner states that we overlooked or misapprehended Dr. Linberg’s testimony that because this was a Phase II trial, one skilled in the art would have believed that DMF had therapeutic activity against MS. Petitioner fails to explain how this statement was misunderstood.

28. On page 15, lines 1 – 6, Petitioner states that we abused our discretion in finding no reasonable expectation of success in using DMF to treat RRMS after learning that BG00012 (DMF) was being used in a clinical

trial. We agree with Patent Owner that Petitioner's argument concerning reasonable expectation of success is new and therefore could not have been overlooked.

29. On page 15, lines 7 – 11, Petitioner states that the Board cited no evidence for its finding that Drugs R&D indicates only a hope that DMF will be useful. We, like Patent Owner, disagree because our finding is supported by Drugs R&D. Decision, page 15.

V. Order

Upon consideration of Petitioner's Request for Rehearing (Paper 26) and Patent Owner's Opposition (Paper 28), and for the reasons given, it is

ORDERED that the Request for Rehearing is *denied*.

PETITIONER:

Robert W. Hahl
Robert Mihail
John Pike
NEIFELD IP LAW, PC
rhahl@neifeld.com
rmihail@neifeld.com
jkpike@neifeld.com

PATENT OWNER:

Micheal Flibbert
Maureen Queler
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
michael.flibbert@finnegan.com
maureen.queler@finnegan.com