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Paper 29
Entered: 23 October 2015

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 Velander 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. *Velander*, 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

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