



Patent Trial and Appeal Board

Informative

Standard Operating Procedure 2

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Paper 121
Entered: 23 July 2013

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

Patent Interference 105,893 McK
Technology Center 1600

JEN-SEN **DUNG**, EMO M. KESKENY
and JAMES J. MENCEL,

Patent 7,851,482 B2,
Junior Party,

v.

HENRY J. **BUEHLER**, WILLIAM E. DUMMITT
ANTHONY MANNINO, DENNIS C. AUBUCHON and HONG GU,

Application 11/915,606,
Senior Party.

Before: FRED E. McKELVEY, RICHARD E. SCHAFER, and
DEBORAH KATZ, *Administrative Patent Judges*.

McKelvey, *Administrative Patent Judge*.

ORDER DENYING DUNG MOTION 3
(Requesting leave to file recently discovered evidence)

Background

1 At the conclusion of Time Period 1, Dung timely filed a motion
2 for judgment based on priority. Paper 104.

3 At the conclusion of Time Period 2, Buehler timely filed a
4 motion for judgment based on priority. Paper 109.

5 Oppositions to both motions are due on at the conclusion of
6 Time Period 3.

7 On 09 July 2013, a conference call was held in response to an
8 email received by the PTAB on 8 July 2013 (10:50 a.m.). The
9 relevant part of the email said:

10 Party Dung has uncovered additional HPLC data
11 relating to the reductions to practice asserted in its motion
12 for priority. Dung would like permission to file a motion
13 requesting belated entry of that evidence. Buehler has
14 indicated that it will oppose the filing of such a motion and
15 entry of the underlying evidence.

16 During the conference call, counsel for Dung explained that
17 new evidence had recently been found by scientists at Johnson
18 Matthey (“JM”)—the original assignee of the involved Dung patent.

19 As a result of discussion during the conference call, Dung was
20 authorized to file a motion seeking leave to present the recently found
21 evidence. Paper 110.

22 Dung Motion 3 was timely filed on 12 July 2013. Paper 112.

23 While Buehler has been authorized to file an opposition, we find
24 that the Dung Motion 3 can be decided adversely to Dung without an
25 opposition.

1 An interlocutory order denying Dung Motion 3 was entered on
2 15 July 2013. Paper 119.

3 This order explains the reason for denying Dung Motion 3.

4 **Facts**

5 The facts are taken in large measure from Dung Motion 3.

6 In deciding the motion, we do not apply “summary judgment”
7 standards typically applied in practice before U.S. district courts. *Cf.*
8 *Basmadjian v. Landry*, 54 USPQ2d 1617 (BPAI 1997).

9 Rather, in filing the motion Dung is under a burden to establish
10 that it is prima facie entitled to the relief it requests. 37 C.F.R.
11 § 41.121(b) (2011).

12 According to Dung, an actual reduction to practice said to have
13 occurred in 2006 is based on preparation of two samples.

14 The two samples are said to be oxymorphone samples
15 containing less than 10 ppm 14-hydroxymorphone (“14-OHM”) as
16 determined by high performance liquid chromatography (“HPLC”).

17 We are told that in the 2006 time frame, scientists at the
18 Analytical Research and Development (“AR&D”) division of Johnson
19 Matthey (“JM”) had two sets of HPLC instruments.

20 The two sets were (1) instruments from Waters and (2) four
21 instruments from Shimadzu.

22 The Waters instruments generated data which is said to have
23 been compatible with an AR&D electronic data storage system called
24 “Empower.”

25 The Shimadzu instruments are identified as “stand-alone”
26 instruments.

1 In 2006, the Shimadzu instruments were used at a West
2 Depford, New Jersey location.

3 In 2012, two of the Shimadzu instruments were moved to a
4 Riverside, New Jersey location.

5 Sometime between January and July 2006, the “Empower”
6 software was updated. We have not been told (1) why an update is
7 relevant or (2) why or how earlier software was inadequate for any
8 purpose relevant to the motion.

9 In the 2006 time frame, some scientists at JM using data
10 generated by stand-alone HPLC instruments, “taped copies of HPLC
11 traces” into their laboratory notebooks. We understand that (1) HPLC
12 results in a paper “trace” being generated and (2) “taped” means that
13 a paper copy of an HPLC trace is physically taped on a page in a
14 laboratory notebook.

15 Jen-Sen Dung is said to have been one of the scientists who
16 taped HPLC copies into his laboratory notebook.

17 Other scientists, including Erno Keskeny, kept separate files
18 containing HPLC traces.

19 In 2006, Robert Hogan is said to have been a Senior AR&D
20 Chemist III.

21 According to Dung, Robert Hogan is said to “have diligently
22 searched for . . . January 2006 HPLC traces which . . . [are said to
23 be] the basis for Erno Keskeny’s January 2006 “conclusion” recorded
24 in his [laboratory] notebook at page 2128-189.

25 The conclusion was that his samples 2128-175 and 2128-189
26 contained either undetectable levels, or less than 10 ppm of 14-OHM.

1 By the end of February 2013, it is said that “they” were unable
2 to locate any of the January data, but were able to retrieve from
3 Empower data obtained by Nisha Patel on sample 2128-189.

4 According to Dung, Nisha Patel was able to confirm that
5 sample 2128-189 contained less than 10 ppm of 14-OHM.

6 Prior to the end of February 2013, Robert Hogan was unable to
7 recall having run any of Dr. Keskeny’s low-ABUK oxymorphone
8 samples of HPLC.

9 However, Robert Hogan is said to have “recently located”
10 HPLC traces from January 26, 2006. How those traces were
11 “recently located” is not explained.

12 The traces apparently are located on page 152 of Hogan
13 laboratory notebook 884.

14 Based on the recently located traces, Robert Hogan now
15 concludes that no 14-OHM could be detected in sample 2128-175.

16 Discussion

17 The rules provide that belatedly filed papers or evidence is not
18 considered. There are two exceptions: (1) a showing of excusable
19 neglect or (2) a PTAB determination that consideration of the late
20 filing would be in the interest of justice. 37 C.F.R. § 41.4(a)(2)
21 (2011).

22 In this case, neither exception applies.

23 (1)

24 We interpret “excusable neglect” in the context of applicable
25 rules relating to practice in interference cases before the PTAB.

26 *Firsthealth of the Carolinas, Inc. v. Carefirst of Maryland, Inc.*,
27 479 F.3d 825, 829 (Fed. Cir. 2007) [the TTAB has discretion to

1 reasonably interpret the meaning of "excusable neglect" in the
2 context of its own regulations, citing *Thomas Jefferson University v.*
3 *Shalala*, 512 U.S. 504, 512 (1994) (an agency's interpretation of its
4 own regulation is given controlling weight unless it is plainly
5 erroneous or inconsistent with the regulation)].

6 In an interference context, where the late filing involves newly
7 discovered evidence, to show excusable neglect a party must
8 establish that the evidence "could not have been earlier discovered,
9 and that the party exercised due diligence in discovering the
10 evidence." Rivise & Caesar, 3 INTERFERENCE LAW AND PRACTICE
11 § 458, page 1962 (1947). See also Rivise, INTERFERENCE PRACTICE
12 § 138 (1932); *Fordyce v. Taisey*, 1903 C.D. 31, 35 (Comm'r Pat.
13 1903) (to warrant reopening of case to take further testimony it must
14 appear that the testimony could not have been previously discovered
15 by exercise of due diligence); *Robinson v. Townsend*, 1902 C.D. 405,
16 406 (Comm'r Pat. 1902) (a clear showing of diligence must be made
17 out); *Dudley v. Blickensderfer*, 1902 C.D. 119, 121 (Comm'r Pat.
18 1902 (same); *Schmiedl v. Booth*, 1891 C.D. 188, 189 (Comm'r Pat.
19 1891) (same).

20 Whether a party exercised the appropriate amount of diligence
21 is a question of fact which must be established by a preponderance
22 of the evidence on a case-by-case basis.

23 The proposed new evidence was in existence at the time Dung
24 (1) prepared its priority case and (2) filed its motion for judgment
25 based on priority.

1 The factual question is whether Dung has established by a
2 preponderance of the evidence that a diligent effort had been made
3 to locate the evidence. The answer in this case is: “No.”

4 All we are told in Dung Motion 3 and the accompanying
5 declaration testimony is that:

6 (1) Hogan and others “have diligently searched for the
7 January 2006 HPLC traces” (Dung Motion 3, page 3) (but no
8 testimony is presented as to what was involved in, or the nature
9 of, any search);

10 (2) “they were unable to locate any of the
11 January [2006] data” (Dung Motion 3, page (but no credible
12 explanation is given as to what effort was made to then locate
13 the data or precisely who “they” might be); and

14 (3) Hogan “recently located HPLC traces” (Dung
15 Motion 3, page 4) (no details are given on precisely how the
16 HPLC traces were “recently located”).

17 The motion and underlying declarations amount to a pleading—
18 not proof. No credible fact-based presentation is made detailing the
19 nature of (1) any search prior to the filing of Dung’s motion for
20 judgment based on priority or (2) any search after the motion was
21 filed.

22 The significance of Shimadzu instruments being moved from
23 one New Jersey location to another has not been shown to be
24 connected with any diligent search.

25 Witness testimony that diligent search was conducted, without
26 details as to the nature of the search, amounts to a mere opinion or

1 conclusion. We do not know factually what steps made up the
2 search. Accordingly, we cannot find that a diligent search was made.

3 Dung has failed to establish excusable neglect.

4 (2)

5 In this case, it would not be in the interest of justice to permit
6 introduction of the newly discovered evidence.

7 Whether the PTAB exercises discretion to implement the
8 interest of justice exception is determined on a case-by-case basis.

9 In this case, the “recently discovered” new evidence comes
10 (1) after Buehler has filed its motion for judgment based on priority
11 and (2) close to the time both parties are to file oppositions to their
12 opponent’s motion for judgment based on priority.

13 In this case the “excusable neglect” and “interest of justice”
14 provisions merge.

15 To permit late filing of evidence by Dung after Buehler has filed
16 its motion for judgment based on priority is highly prejudicial to
17 Buehler.

18 If the recently discovered evidence were to be admitted, then
19 Buehler should have an opportunity to (1) consider the evidence on
20 the merits and (2) determine what additional evidence it might need
21 for its priority case. *Rivise & Caesar*, at page 1972.

22 We cannot imagine that Buehler would not want to cross-
23 examine witnesses testifying on the merits with respect to the newly
24 discovered evidence. Buehler indicated as much in the conference
25 call.

26 We perceive of no legitimate justification in this case to
27 reconcile (1) a lack of diligence on the part of Dung with (2) requiring

1 Buehler to expend additional resources to answer the newly
2 discovered evidence. 37 C.F.R. § 41.2 (2011) (requiring that the
3 rules be interpreted to secure a just, speedy and *inexpensive*
4 resolution of contested cases before the PTAB).

5 This is not an appropriate case for the PTAB to exercise its
6 discretion by authorizing the new evidence based on an “interest of
7 justice” theory.

8 **Order**

9 Upon consideration of Dung Motion 3, and for the reasons
10 given, it is

11 **ORDERED** that Dung Motion 3 is *denied*.

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