Paper No. 64
Filed: June 30, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC,

PETITIONER,

V.

CELGENE CORPORATION,

PATENT OWNER.

Case IPR2015-01096
Patent 6,315,720

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE

Patent Owner has submitted a sprawling motion to exclude that encompasses, *inter alia*, Patent Owner's own exhibits and certain evidence that Patent Owner merely argues is unpersuasive (rather than objectionable on evidentiary grounds). Petitioner respectfully submits that Patent Owner's motion is meritless in its entirety and may be summarily dismissed. Petitioner nevertheless hereby responds to each of Patent Owner's arguments in turn.

I. THE BOARD SHOULD DENY PATENT OWNER'S MOTION TO EXCLUDE EXHIBIT 1024 ("MUNDT") BECAUSE IT IS ADMISSIBLE UNDER FED. R. EVID. 703, BECAUSE IT IS NOT HEARSAY, AND BECAUSE PATENT OWNER'S OBJECTIONS ARE MOOT

Exhibit 1024 ("Mundt") is a publication cited in the Petition in part to corroborate its expert's testimony and was credited by the Board in its Decision instituting *IPR*. (*See* Paper 21 at 15, 20.) It was also cited in the declarations of both of Celgene's experts. (*See* Frau Decl. (Ex. 2059) at 41 ("Mundt discloses the use of IVR in telephone surveys for research and treatment of compulsive disorders"); DiPiro Decl. (Ex. 2060) at 23-24, 37.).)

Exhibit 1024 is admissible under Federal Rule of Evidence 703 as material relied upon by Patent Owner's expert witnesses in forming their opinions. Fed. R. Evid. 703; *see, e.g.*, *Nestle*, IPR2015-00249, Paper 76, 2016 Pat. App. LEXIS 4337, at *18–20 (finding material relied upon by expert "admissible under Fed. R. Evid. 703" "even if [it] is hearsay").

The foregoing is dispositive of Patent Owner's objections. Petitioner further notes, however, that the Board may also reject Patent Owner's objections on the basis that the statements are not hearsay because they are not offered for the truth of the matter asserted. Fed. R. Evid. 801(c). Patent Owner's motion confusingly treats Petitioner's "argu[ment]" and statements from Exhibit 1024 together as one and the same (*see* Paper 60 at 2), but this is not so. Petitioner cites Exhibit 1024 as demonstrative evidence that a POSA would have known to use IVR in a variety of settings. (*See* Paper 52 at 26.) The fact that Mundt expressly contemplates the use of IVR for different applications corroborates Petitioner's expert's testimony. Exhibit 1024 contradicts Patent Owner's argument to the contrary, even regardless of whether the various statements in Exhibit 1024 are in fact true Petitioner thus offers Patent Owner's Exhibit 2063 for a non-hearsay purpose. *See* Fed. R. Evid. 801(c).

Finally, Petitioner further notes that the Board may dismiss Patent Owner's objections as moot. The Board has already correctly held "the evidence of record demonstrates that one skilled in the art had reason to use interactive voice response systems to conduct patient surveys." (Paper 21 at 20.) The Board thus need not reach Patent Owner's objections concerning Exhibit 1024 in order to confirm the determination already made by the Board in its institution decision. *See, e.g.*, *Samsung*, IPR2014-00408, Paper No. 48, 2015 Pat. App. LEXIS 12520, at *34

(same; further stating "We agree that the Board, sitting as a non-jury tribunal, is well-positioned to assign appropriate weight to the evidence without the need for formal exclusion."). The Board may accordingly dismiss Patent Owner's objections as moot.

II. THE BOARD SHOULD DENY PATENT OWNER'S MOTION TO EXCLUDE EXHIBIT 1076 ("FDA MEETING PART 1") BECAUSE IS ADMISSIBLE UNDER FED. R. EVID. 703, BECAUSE IT IS A PUBLIC RECORD, BECAUSE IT IS NOT HEARSAY, AND BECAUSE IT IS ADMISSIBLE UNDER THE RESIDUAL HEARSAY EXCEPTION,

Exhibit 1076 ("FDA Meeting Part 1") is an official FDA meeting transcript cited, relied upon, and considered a credible source by Petitioner's expert Dr. Jeffrey Fudin. (*See* Fudin Decl. (Ex. 1021) at 18-20)[1] (discussing a POSA's knowledge of the Clozaril® and Accutane® programs.)

Exhibit 1076 is admissible under Federal Rule of Evidence 703 as material relied upon by Petitioner's expert witness. Fed. R. Evid. 703; *see, e.g.*, *Nestle*, IPR2015-00249, Paper 76, 2016 Pat. App. LEXIS 4337, at *18–20 (finding material relied upon by expert "admissible under Fed. R. Evid. 703" "even if [it] is hearsay").

Exhibit 1076 is also admissible under the public records hearsay exception. Fed. R. Evid. 803(8). The document is a record of activities at the FDA, and Patent Owner has not shown that the document lacks trustworthiness (indeed Patent

[1] Exhibit 1076 ("FDA Meeting Part 1") is referenced as Exhibit 1013 in Ex. 1021.

Owner itself introduced the document in a related proceeding, IPR2015-01092). *See id.*

The foregoing is dispositive of Patent Owner's objections. Petitioner further notes, however, that the Board may also reject Patent Owner's motion on the basis that it identifies no hearsay statements that are offered for the truth of the matter asserted. Fed. R. Evid. 801(c). First, Patent Owner's motion does not identify with specificity *any* statement in Exhibit 1076 that it is challenging as hearsay. (*See* Paper 60 at 2.). *But see* PTO Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48767 (Aug. 14, 2012) ("A motion to exclude must explain why the evidence is not admissible…."). Further, Petitioner does not quote or cite any statement in Exhibit 1076 at 7 and 137 for its truth; rather, Petitioner cites the transcript as evidence of the knowledge of a POSA relating to two programs in the prior art. Petitioner thus offers Patent Owner's Exhibit 1076 for a non-hearsay purpose. *See* Fed. R. Evid. 801(c).

Petitioner further submits that even if its citation to Exhibit 1076 somehow constituted hearsay—which it does not—the evidence would still be admissible under the residual hearsay exception. Fed. R. Evid. 807. The FDA meeting transcript (1) is a public record with circumstantial guarantees of trustworthiness; (2) is offered as evidence of a material fact, i.e. that a POSA knew about Clozaril® and Accutane®; (3) is the most probative evidence on this point, as it is conclusive

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