Paper No. __
Filed: July 15, 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

PATENT OWNER REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE

Patent Owner ("Celgene") submits this reply in response to Petitioner's ("CFAD") opposition to Celgene's Motion to Exclude. *See* Paper 64 ("Opp.").

I. CFAD Relies on Exs. 1024 and 1076 for Hearsay Purposes

CFAD relied on Exs. 1024 and 1076 for hearsay purposes. *See* Paper 60 ("Mtn.") 1-3. The arguments in CFAD's opposition lack merit. *First*, CFAD's use of the exhibits is not admissible under Fed. R. Evid. 703, as CFAD alleges. Opp. 1, 3. "[Rule] 703 permits an ***expert***" to rely on hearsay. *Nestle Healthcare Nutrition, Inc. v. Steuben Foods, Inc.*, IPR2015-00249, 2016 Pat. App. LEXIS 4337, *18–20 (June 2, 2016) (emphasis added). Here, there is ***no expert testimony*** concerning the portions of these exhibits cited in CFAD's reply because Dr. Fudin did not address them initially, and CFAD did not submit an expert declaration with its reply. *See* Mtn. 2.

Second, CFAD argues that it does not rely on Exs. 1024 and 1076 for hearsay purposes because they are allegedly "demonstrative evidence" of CFAD's arguments, "regardless of whether the various statements [in them] are in fact true." Opp. 2; *see also id.* at 4. If the statements are not true, however, then they are not "demonstrative evidence" for CFAD's attorney argument. CFAD's circular logic does not change the fact that its use of the exhibits is not admissible under Rule 801(c). Further, CFAD's argument regarding how it allegedly uses Ex. 1076 at 7 and 137 (*see* Opp. 4) is irrelevant to Celgene's objection regarding CFAD's

use of Ex. 1076 at 137 and 250 (Mtn. 2).[1] Specifically, Celgene did not lodge a hearsay objection to CFAD's use of the alleged "transcript as evidence of the knowledge of a POSA relating to two programs in the prior art," as CFAD alleges. *Compare* Opp. 4 *with* Mtn. 2.

Third, CFAD argues that Celgene's objections regarding Ex. 1024 are moot because the Board made certain initial findings in the Institution Decision. Opp. 2-3. CFAD ignores, however, that "the Board is not bound by any findings made in its Institution Decision." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016). Indeed, the Federal Circuit has noted the "significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial." *Id.*

Fourth and finally, CFAD argues that its use of Ex. 1076 should be permitted under the residual hearsay exception. Opp. 4-5. That exception is "reserved for 'exceptional cases,' and is not 'a broad license on trial judges to admit hearsay statements that do not fall within one of the other exceptions.'" *Neste Oil OYJ v. Reg Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 10 (Mar. 12, 2015) (citation omitted). Further, for CFAD's use of Ex. 1076 to be admissible

[1] Despite CFAD's claim (Opp. 4), Celgene's motion clearly identifies the statements CFAD relies upon at pages 137 & 250 of Ex. 1076 as hearsay. Mtn. 2.

under the residual exception, it must be more probative than other evidence CFAD could have obtained through reasonable efforts. Fed. R. Evid. 807(3). CFAD argues that Ex. 1076 is the "most probative evidence . . . as it is conclusive proof that Patent Owner itself discussed [Clozaril and Accutane]." *See* Opp. 4-5. Of course, this ignores the fact that Celgene's objection is premised on something else entirely, namely CFAD's reliance on Ex. 1076 (at 137 and 250) "to allege that statements were made in Ex. 1076 'in which the link between teratology and genetic testing was made explicit.'" Mtn. 2. CFAD's residual hearsay exception argument is silent on this issue. It lacks merit for this additional reason.

II. CFAD Does Not Contest Celgene's Objection to Ex. 1075 at 168:5-11, 166:3-7, 306:4-10

CFAD had no basis to rely on this testimony because it has nothing to do with the challenged patent. *See* Mtn. 3. As such, CFAD correctly does not challenge Celgene's objection. *See generally* Opp.

III. CFAD Does Not Contest Celgene's Objection to Ex. 1072 and Ex. 2061 at 515:1-516:16

Celgene objected to the above-referenced exhibits because Ex. 1072 was published 11 years after the challenged patent's filing date, and is therefore irrelevant to whether a person of ordinary skill ("POSA") would have had an alleged motivation to arrive at the claimed inventions. *See* Mtn. 5-7. CFAD ignores this argument entirely, and instead focuses on "unexpected results," which

are not even at issue in this proceeding. *See* Opp. 6-7. Exhibit 1072 and the corresponding testimony should be excluded.

IV. Celgene's Relevancy Objections Go to Admissibility, not Weight

CFAD argues that Celgene's relevancy objections "challenge the sufficiency" of CFAD's evidence. Opp. 5. Not so. Put simply, "[i]rrelevant evidence is not admissible." Fed. R. Evid. 402. Celgene's objections challenge the admissibility of irrelevant evidence that cannot make any fact of consequence in determining the action more or less probable, as required by Fed. R. Evid. 401.

A. CFAD Does Not Contest Celgene's Argument that Exs. 1073 and 1076 are Not Prior Art

CFAD argues that Celgene's objections regarding non-prior art go to weight, not admissibility. Opp. 6, 8. CFAD, however, does not provide any basis for its argument. The obviousness inquiry requires determining what would have been known by a POSA ***at the time of the invention***. *See* Mtn. 3-4, 7-8. CFAD does not dispute that a POSA could not have had access to Exs. 1073 and 1076 at the time of the claimed inventions because they are not prior art. The exhibits are irrelevant to obviousness and are therefore inadmissible. *See* Mtn. 3-4, 7-8.

B. Exs. 1075 and 1077-81 Are Irrelevant Because They Do Not Cast Doubt On Dr. Frau's Credibility, as CFAD Alleges

Celgene objected to certain portions of Ex. 1075, and Exs. 1077-81 in their entirety, as irrelevant. *See* Mtn. 7. CFAD's only argument for admissibility is that they allegedly "cast doubt on the credibility of Dr. Frau's testimony." Opp. 7.

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