Paper No. __
Filed: June 23, 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 IPR2015-01102
Patent 6,315,720

_____

PATENT OWNER MOTION TO EXCLUDE EVIDENCE

I. PRECISE RELIEF REQUESTED

Patent Owner, Celgene Corporation ("Celgene"), hereby moves pursuant to 37 C.F.R. § 42.64(c) to exclude certain evidence relied upon by Petitioner, Coalition for Affordable Drugs VI LLC ("CFAD") in its Reply (Paper 54). CFAD's Reply relies on hearsay, irrelevant evidence, and mischaracterizations of Celgene's expert's and inventor's statements. The objected-to portions should be excluded.

II. MATERIAL FACTS

On May 27, 2016, CFAD filed its Reply. Five business days later, Celgene served and filed its objections to the evidence cited in CFAD's Reply under 37 C.F.R. § 42.64(b)(1). *See* Paper 57 ("Objections"); Ex. 2069. CFAD did not serve any supplemental evidence, despite having had the opportunity to do so.

III. ARGUMENT

A. CFAD improperly relies on hearsay

Hearsay is an out-of-court statement offered to prove the truth of the matter asserted, and is inadmissible unless an exception applies. Fed. R. Evid. 801(c), 802. CFAD's Reply relies on several exhibits for impermissible hearsay purposes, and no exception applies. CFAD's use of these exhibits should be excluded.

1. Exhibit 1012 ("FDA Meeting Part 1") at 137 and 250 (Objections ¶15)

CFAD relies on Ex. 1012 at 137 and 250 to allege that statements were made in Ex. 1012 "in which the link between teratology and genetic testing was made explicit." Reply at 23. This is hearsay. CFAD is offering the out-of-court statements to prove the truth of the matter asserted. And there is no evidence concerning what the cited portions of Ex. 1012 mean to a POSA, despite CFAD having had the opportunity to submit a Reply expert declaration, but choosing not to do so. Thus, Celgene moves to exclude Ex. 1012 at 137 and 250 under Fed. R. Evid. 801-802.

2. Exhibit 1017 ("Mundt") at 611-612 (Objections ¶17)

CFAD relies on Ex. 1017 at 611-612 to argue that: (1) alleged "advantages of the use of IVR over traditional interactions with physicians include 'around the clock' accessibility and that '[m]any individuals will disclose sensitive information to a computer that they would be reluctant to discuss with another person'"; and (2) "Mundt teaches that IVR can be used in a variety of settings." Reply at 24. This is hearsay. CFAD is offering the out-of-court statements to prove the truth of the matter asserted. And there is no evidence concerning what the cited portions of Ex. 1017 mean to a POSA, despite CFAD having had the opportunity to submit a Reply expert declaration, but choosing not to do so. Thus, Celgene moves to exclude Ex. 1017 at 611-612 under Fed. R. Evid. 801-802.

B. CFAD improperly relies on irrelevant evidence

Evidence is relevant if: (1) it has any tendency to make a fact more or less probable than it would be without the evidence; and (2) the fact is of consequence in determining the action. Fed. R. Evid. 401. CFAD's Reply cites several exhibits that are irrelevant for the purposes for which they are being offered.

1. Exhibit 1086 at 168:5-11, 166:3-7, 306:4-10 (Objections ¶1)

CFAD relies on Exhibit 1086 at 168:5-11, 166:3-7, and 306:4-10 for the proposition that "Dr. Frau testified that her own proposed POSA would not be able to design the claimed methods of the '720 patent." Reply at 3-4. This is false.

The cited testimony does not concern the '720 patent, let alone whether any POSA would be able to design the inventions claimed in the '720 patent. Rather, both the questions and answers explicitly relate only to U.S. Patent No. 6,045,501 (the "'501 patent"). Thus, Celgene moves to exclude Exhibit 1086 at 168:5-11, 166:3-7, and 306:4-10 under Fed. R. Evid. 401-402 because it is not relevant to any material issue of fact in dispute regarding the '720 patent, which is the only patent at issue in this IPR.

2. Exhibit 1084 (Objections ¶4)

Exhibit 1084 is a titled, "2013 Rho Chi Lecture: Writing the Headlines of Tomorrow," which is authored by Celgene's expert, Dr. Joseph T. DiPiro, PharmD. CFAD relies on Ex. 1084 in an attempt to counter Dr. DiPiro's opinion that "someone with Dr. Fudin's POSA's qualifications would have very little, if

any, experience with restricted distribution systems, such as those claimed in the '720 patent. They would certainly not be able to design or implement such systems." *See* Reply at 5; Ex. 2060 ¶ 17. But Ex. 1084 was published in 2013—13 years after the filing date of the '720 patent—and is not prior art to the '720 patent. Further, CFAD did not adduce any testimony showing that Dr. DiPiro's statements in Ex. 1084 would have been true for a pharmacist at any time relevant to the '720 patent's filing date.

Thus, Celgene moves to exclude Ex. 1084 under Fed. R. Evid. 401-402 because it is not relevant to any material issue of fact in dispute. It does not provide any evidence of the level of skill or knowledge of a POSA ***at the time of the invention***. *See Chiuminatta Concrete Concepts. v. Cardinal Indus.*, 145 F.3d 1303, 1313 (Fed. Cir. 1998) (finding post-filing-date publication "not relevant to . . . obviousness" because it did not reflect information known in the prior art).

3. Exhibit 2061 at 190:15-18 and 192:10-14 (Objections ¶3)

Exhibit 2061 is the deposition transcript of CFAD's expert, Dr. Jeffrey Fudin. CFAD relies on Ex. 2061 at 190:15-18 and 192:10-14 to argue that "Dr. Fudin testified that his proposed POSA would be a clinician who 'could' design successful methods for risk management in delivering medication by drawing upon the support of a 'multi-disciplinary team.'" Reply at 4. CFAD argues that this testimony supports Dr. Fudin's POSA being the correct POSA.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.