Paper No. __
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 IPR2015-01103
Patent 6,315,720

_____

PATENT OWNER OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE

Patent Owner Celgene Corporation ("Celgene") hereby opposes Petitioner Coalition for Affordable Drugs VI LLC's ("CFAD") motion to exclude certain testimony from its declarant, Dr. Jeffrey Fudin, and Celgene's reliance on the same in its Patent Owner Response. *See* Paper 64.

CFAD seeks to exclude highly relevant testimony in which Dr. Fudin admitted that CFAD's proposed person of ordinary skill in the art ("POSA") would not have been able to design or implement the claimed inventions. *See id.*

According to CFAD, the testimony that it seeks to exclude is irrelevant because Celgene allegedly argues that the challenged patent "claims systems, when in fact [it] only claims methods for delivering a drug to a patient." *Id.* at 1. CFAD's motion relies on the false premise that Dr. Fudin was "confus[ed]" regarding Celgene's alleged "undefined reference to 'systems'" during Dr. Fudin's deposition. *Id.* at 2. But as explained below, the full testimony that CFAD seeks to exclude shows that there was no such confusion. Nor were the "system[s]" discussed during Dr. Fudin's deposition "undefined," as CFAD alleges. *Id.* Dr. Fudin understood the questions, and also understood what is claimed in the challenged patent; he simply answered Celgene's questions in a way that harms CFAD's case by demonstrating that CFAD's proposed POSA is incorrect.

Indeed, Celgene started the line of questioning that CFAD seeks to exclude by clearly defining what is claimed and what is meant by "system[s]" within the

testimony:

Q. But let me be clear. The ***claims*** of the patent are talking about ***methods*** that involve distribution from start to finish, from the manufacturer to the patient, right?

A. Yes.

Q. Okay. If we're designing ***such a system*** for dangerous drugs and the goal and the focus of the entire patent is on avoiding adverse events associated with such dangerous drugs, right?

A. Right.

Q. If we're looking at who the POSA is in that circumstance, I'm trying to understand why you think in that circumstance all we need is a pharmacy – a pharmacist?

A. ***Because the pharmacist doesn't need to design those systems***. The pharmacist needs to know how to use those systems in real time. And they use those systems.

* * *

Q. So your pharmacist POSA does not need to be able to design the full system ***claimed*** in the '501 patent?

A. They don't need to know how to design it, ***no***.

Q. And they don't need to know how to design the full system ***claimed*** in the '720 patent?

A. ***No***.

* * *

Q. And you had said your POSA did not need to be able to design the ***claimed*** systems, right?

A. ***Yes***.

Ex. 2061 at 199:10-200:3, 201:1-10, 328:25-329:2 (emphasis added). Thus, the use of "system[s]" clearly refers to the claimed methods because Celgene referred to the claimed methods as "such a system." Dr. Fudin was not confused. At no point did he say or even indicate that he was unsure about whether the "system[s]" being discussed were explicitly referring to the claimed methods.

Instead, Dr. Fudin admitted that the claims of the patents-at-issue cover certain systems for controlling distribution of dangerous drugs like thalidomide:

> Q. You don't have any reason to believe that the three systems we're talking about here – original S.T.E.P.S., S.T.E.P.S., Enhanced S.T.E.P.S., and the Thalomid REMS – you don't have any reason to believe that the claims of the '501 and '720 patent do not cover those three specific systems, right?
>
> A. I believe they're all covered.

Ex. 2061 at 73:1-8. Dr. Fudin unequivocally understood what is claimed.[1]

Instead of acknowledging Dr. Fudin's understanding, CFAD seeks to conflate the fact that he did not know ***why*** he was being asked if CFAD's proposed

[1] Notably, Dr. Fudin alleges that his expertise is in distribution ***systems***, further emphasizing that methods and systems for restricting distribution of dangerous pharmaceuticals are interchangeable in this case. *See* Ex. 1027 ¶13.

POSA could design the claimed inventions (*see* Paper 64 at 2 (citing Ex. 2061 at 200:4-17)) with his understanding of ***what*** the claimed "system" was. But as evidenced from the testimony, Dr. Fudin clearly understood what was claimed and what he was being asked regarding the claims, and whether his proposed POSA could have designed what is claimed. CFAD's motion should be denied. *See Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2012-00022, 2014 WL 4381564, at *33-34 (Sept. 2, 2014) (denying motion to exclude declarant testimony that was premised on alleged witness confusion).

Indeed, if anything, the fact that Dr. Fudin did not understand ***why*** he was being asked certain questions merely highlights his unfamiliarity with how to define a POSA. Indeed, Dr. Fudin testified that he arrived at his definition of a POSA by "Googl[ing] it," or going "back to a previous deposition and look[ing] at what [he] put down as a POSA." *See* Ex. 2061 at 161:17-163:12.

Here, Dr. Fudin repeatedly admitted that CFAD's proposed POSA would not have been capable of designing or implementing the ***claimed inventions***. *See id.* at 193:12-194:10, 201:1-10, 246:17-247:2, 328:19-329:9. Instead, as CFAD admits, at most, Dr. Fudin testified that CFAD's proposed POSA allegedly "'could' design successful methods for risk management in delivering medication by drawing upon the support of a 'multi-disciplinary team.'" *See* Paper 64 at 2-3.

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.