Paper No. __
Filed: June 6, 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 OBJECTIONS TO EVIDENCE SUBMITTED BY PETITIONER PURSUANT TO 37 C.F.R. § 42.64(b)(1)

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Celgene Corporation ("Celgene") objects as follows to the admissibility of evidence relied upon by Petitioner in its May 27, 2016 Reply (Paper 54).

1. Exhibit 1086 at 168:5-11, 166:3-7, and 306:4-10 is objected to under Fed. R. Evid. 401-402 because it is irrelevant to whether Dr. Lourdes Frau's POSA would have been able to design the inventions claimed in U.S. Patent. No. 6,315,720 (the "'720 patent"). The cited testimony does not concern whether any POSA would be able to design the inventions claimed in the '720 patent.

2. Exhibit 1086 at 168:5-11 and 166:3-7 is objected to under Fed. R. Evid. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading and unfairly prejudicial. Exhibit 1086 at 168:5-11 and 166:3-7 is also objected to under Fed. R. Evid. 106 because Petitioner only introduces part of Dr. Frau's deposition testimony on this issue and, in fairness, another portion of that deposition testimony ought to be considered at the same time. Petitioner's use of Exhibit 1086 at 168:5-11 and 166:3-7 is objected to under Fed. R. Evid. 401-403 because it mischaracterizes Dr. Frau's full testimony on this issue. Specifically, Dr. Frau explained that her POSA would not have been able to design the inventions claimed in U.S. Patent No. 6,045,501 (the "'501 patent") because "[s]uch POSAs would not have had the information that the inventors had. If my POSA would have the information, then they would have been able to - -

they would have been able to, but they didn't have what the inventors had." Ex. 1086 at 333:6-25. Dr. Frau further testified that her POSA would have been capable of designing the inventions claimed in the '501 patent because they had the skills to do so. *Id.* at 334:3-335:8.

3. Exhibit 2061 at 190:15-18 and 192:10-14 is objected to under Fed. R. Evid. 401-402 because that testimony is not relevant to any material issue of fact in dispute in this IPR. Whether Dr. Jeffrey Fudin's POSA could design an unspecified "risk management program that was successful" is irrelevant to whether his POSA could design the inventions claimed in the '720 patent, which is at issue in this IPR.

4. Exhibit 1084 is objected to under Fed. R. Evid. 401-402 because it is not relevant to any material issue of fact in dispute in this IPR. Exhibit 1084 was published in 2013 (13 years after the filing date of the '720 patent), and is not prior art to the '720 patent. Exhibit 1084 provides no evidence of Dr. Joseph DiPiro's opinion of a pharmacist's role at any time relevant to the validity of the '720 patent.

5. Exhibit 1086 at 75:22-77:2, 81:12-83:5, 129:11-133:7, 152:12-154:21, and 185:12-187:8 is objected to under Fed. R. Evid. 401-402 because it is irrelevant to the issue of Dr. Frau's credibility. The fact that Dr. Frau carefully

considered Petitioner's counsel's questions and asked for clarification when the questions were confusing is irrelevant to Dr. Frau's credibility.

6. Exhibits 1087-1091 are objected to under Fed. R. Evid. 401-402 because they are irrelevant to the issue of Dr. Frau's credibility. The fact that Dr. Frau carefully considered Petitioner's counsel's questions and asked for clarification when the questions were confusing is irrelevant to Dr. Frau's credibility.

7. Exhibit 1086 at 307:3-4 is objected to under Fed. R. Evid. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading and unfairly prejudicial. Exhibit 1086 at 307:3-4 is also objected to under Fed. R. Evid. 106 because Petitioner only introduces part of Dr. Frau's answer to a deposition question and, in fairness, both the full answer and the question that preceded it should be considered at the same time. Petitioner's use of Exhibit 1086 at 307:3-4 is objected to under Fed. R. Evid. 401-403 because it mischaracterizes Dr. Frau's full testimony on this issue. Specifically, the question that led Dr. Frau to testify that "her interpretation of prior art may not be accurate" was whether she "agree[d] that the '501 patent is prior art to the '720 patent." Ex. 1086 at 306:11-12. Dr. Frau's full answer was: "I am not a lawyer, so my interpretation of prior art may not be accurate. It may not even be the same that you have. So . . . In my interpretation of your statement prior art and what I think

is prior art, even though I'm not a lawyer, I'm going to say it may have been so - - but I'm not a lawyer, so my interpretation of prior art and yours may be different." *Id.* 307:3-11.

8. Exhibit 1086 at 204:10-18 is objected to under Fed. R. Evid. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading and unfairly prejudicial. Exhibit 1086 at 204:10-18 is also objected to under Fed. R. Evid. 106 because Petitioner only introduces part of Dr. Frau's deposition testimony on this issue and, in fairness, another portion of that deposition testimony ought to be considered at the same time. Petitioner's use of Exhibit 1086 at 204:10-18 is objected to under Fed. R. Evid. 401-403 because it mischaracterizes Dr. Frau's full testimony on this issue. Specifically, the very next question and answer state: "Q. My last question was just about what you have written in your report in paragraph 70, which is that terms are to be given their broadest reasonable constructions as would be understood by a POSA . . . And do you agree with that statement? A. Yes, yes, I do. But I wasn't sure if that was the follow-up to your previous question. So I wasn't totally sure whether you were trying to say, well, that refers to the previous question. So I had to say no, I wasn't totally sure which way you were going. So if you were only addressing that one statement, I agree." Ex. 1086 at 204:19-205:9.

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