Paper No. 67 Filed: July 15, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC,

PETITIONER,

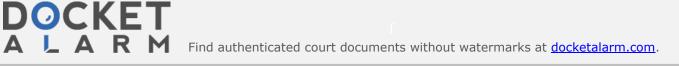
V.

CELGENE CORPORATION,

PATENT OWNER.

Case IPR2015-01096 Patent 6,315,720

PETITIONER'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)



Patent Owner responds to Petitioner's motion to exclude with a straw-man argument that mischaracterizes Petitioner's motion as "rel[ying] on the false premise that [Petitioner's expert] Dr. Fudin was 'confus[ed].'" (Response (Paper 63) at 1.) Of course, Petitioner never made this argument. (*See* Motion (Paper 61) at 1–3.) Instead, Petitioner argued that *Patent Owner's counsel* appeared confused, basing virtually the entirety of his questions on a "system" that is not claimed by any of the patents at issue in these related *inter partes* review proceedings. (*See* Motion at 1, 3 ("All of this evidence suffers from the same deficiency of form concerning Patent Owner's counsel's questions regarding 'systems' that are not claimed by the '720 Patent."). As a result, Patent Owner now finds itself relying on a transcript that contains little discussion of the methods actually claimed by the patents under review by the Board.

Petitioner recognizes that it is possible that Patent Owner's counsel was not confused, but rather was referring to "systems" instead of "methods" for some rhetorical or other purpose. Petitioner does not know the intentions of Patent Owner's counsel. Petitioner does know, however, that this choice of words is a distinction with a difference. As the Federal Circuit has recognized, it is well-settled that "the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1302 (Fed. Cir. 2005) (citation omitted).

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The testimony Patent Owner cites in opposition supports Petitioner's objection. (*See* Response at 2.) As a threshold matter, Patent Owner conveniently omits the beginning of its counsel's questions, which open thus:

Q. I am not sure I follow, and I also am not sure where you're going with administrative degree.

(Ex. 2061 at 199:8–9.) At the outset, therefore, Patent Owner's counsel himself expresses confusion regarding the uncertain footing of his questions and Dr. Fudin's responses. The subsequent testimony, similarly, fares no better. Patent Owner's counsel first acknowledges that the "[t]he claims of the patent are talking about methods" (*id.* at 199:10–11), but then insists on turning to questions regarding "a system[.]" (*Id.* at 199:17–17; *see also id.* at 198:7–10 (Q: "So we're talking about designing a system for a drug at large in all circumstances. Okay?").) Dr. Fudin responded to these questions by stating "right" (*id.* at 199:20), "okay" (*id.* at 198:10), and—ultimately—"I'm not really sure what this inquiry is about." (*Id.* at 200:8–9.)

Further context from the deposition deepens the confusion of Patent Owner's questions. Patent Owner's counsel questioned Dr. Fudin throughout the deposition regarding, for example, "computerized billing and patient record systems" (*id.* at 128:19–25), "computer systems" (*id.* at 138:11–14.), and prior art's inclusion or omission of "a DOS system or the Windows system." (*Id.* at

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301:9–12.) As Dr. Fudin's declaration states, Dr. Fudin has experience with such systems (*see*, *e.g.*, Ex. 1021 at 4.)—but Dr. Fudin never testified that he or a POSA would be capable of constructing such a system. (*See id.*) For such matters, Dr. Fudin testified that a POSA would "work collaboratively with other team members that have their own unique specialized skillset, training, and knowledge base[.]" (*Id.* at 7; *see also* Ex. 2061 at 516:17–529:1 (further explaining knowledge of POSA and ability of POSA to design the claimed inventions with collaborative team).) In fact, Dr. Fudin specifically testified regarding a POSA's ability to design "systems" that the POSA need not be able to "actually code it in a computer" (Ex. 2061 at 517:7–518:8), but that everything claimed by the patent "fits squarely with[in] the duties of a registered pharmacist at the time of this patent." (*Id.* at 510:11–521:1; *see also id.* at 524:12–529:1.)

Petitioner seeks limited relief: the exclusion of questions and testimony relied upon by Patent Owner regarding "systems" that are not actually claimed by the patents under review. Petitioner also recognizes that the Board has stated, correctly, that "[t]he PTAB, sitting as a non-jury tribunal with administrative expertise, is well-positioned to determine and assign appropriate weight to evidence presented." *Ariosa Diagnostics v. Isis Innova Ltd.*, IPR2012-00022, Paper 166, 2014 Pat. App. LEXIS 6356, *84–85 (PTAB Sept. 2, 2014); *see also, e.g.*, *Baxter Healthcare Corp. v. Millenium Biologix, LLC*, IPR2013-00582, Paper 48,

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2015 Pat. App. LEXIS 2563, *73 (PTAB Mar. 18, 2015) ("Having been alerted to the dispute by Patent Owner, through its motion and again during the oral hearing, we have taken great care to weigh all of [the evidence.]"). If the Board decides not to exclude the objectionable evidence identified by Petitioner's motion, Petitioner respectfully submits that the Board should assign no weight to the evidence on the grounds that it is irrelevant, confusing, misleading, and unfairly prejudicial. *See* Fed. R. Evid. 401–403.

July 15, 2016

Respectfully Submitted,

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