Paper No. 63
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

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

Petitioner hereby moves pursuant to 37 C.F.R. § 42.64(c) and the Federal Rules of Evidence to exclude certain testimony elicited in Patent Owner's cross-examination of Dr. Jeffrey Fudin on the basis that it is irrelevant due to the confusing, misleading, and unfairly prejudicial nature of the questions posed. *See* Fed. R. Evid. 401–403; 37 C.F.R. § 42.62(a). In particular, Petitioner moves to exclude the deposition testimony of Dr. Jeffrey Fudin (Ex. 2061) ("Fudin Dep.") at 199:8–201:11, 328:19–329:2, and Patent Owner's arguments thereon in its Response (Paper No. 41) at 15–16. Petitioner's counsel timely objected to this testimony at deposition. (*See* Fudin Dep. at 199:15, 200:7, 200:15, 201:4, 201:11, 328:21.)

In its Response, Patent Owner misleadingly asserts that Dr. Fudin "insisted that his POSA 'doesn't need to design [the claimed] systems.'" (Paper No. 41 at 15 (citing Fudin Dep. at 199:8–200:9).) Patent Owner's argument, however, relies on the false pretense that U.S. Patent No. 6,315,720 ("'720 Patent") claims *systems*, when in fact the '720 Patent instead only claims *methods* for delivering a drug to a patient. (*See* Ex. 1001 at claims; Petitioner's Reply (Paper No. 54) at 4.) *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1302 (Fed. Cir. 2005) ("the concept of 'use' of a patented ***method*** or process is fundamentally different from the use of a patented ***system*** or device") (emphasis added), *citing In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing "the distinction between a claim to a

product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps….").

The confusing nature of Patent Owner's undefined reference to "systems" was apparent at Dr. Fudin's deposition, and was even expressly noted by Dr. Fudin:

> Q. Do you think the inquiry here is about how to use systems or about how to come up with the system in the first place?
>
> MS. SPIRES: Object to form.
>
> A. I'm not really sure what this inquiry is about.
>
> Q. (By Mr. Chalson) You rendered opinions about whether or not claims are obvious, and you're not sure whether the inquiry is about how to use a system versus how to design a system?
>
> A. I'm not sure --
>
> MS. SPIRES: Object to form.
>
> A. I'm not sure why you're asking me this series of questions….

(Fudin Dep. at 200:4–17.) Patent Owner's counsel did not attempt to cure the form objections raised by Petitioner's counsel.

Dr. Fudin testified that his 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." (Fudin Dep. at 190:15–18, 192:10–14; Ex. 1002 ¶ 16; *see also* Paper No. 54 at 4-5.) Dr. Fudin did not testify that his POSA would be a computer engineer or administrator without clinical experience. (*See* Paper No. 54 at 4.) Patent Owner's questions at Dr. Fudin's deposition and corresponding reliance thereon in its Response concerning the ability of Dr. Fudin's POSA to design undefined "systems," are confusing and bear no relevance to the ability of a POSA to practice the methods that are actually claimed by the '720 Patent.

Pursuant to Federal Rules of Evidence 401–403, the Board should exclude the deposition testimony of Dr. Fudin at 199:8–201:11, 328:19–329:2, and Patent Owner's arguments thereon in its Response (Paper No. 41) at 15–16. 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. None of the resulting testimony makes a fact of consequence to this proceeding more or less probable. *See* Fed. R. Evid. 401–402. The irrelevant testimony and Patent Owner's arguments thereon are confusing, misleading, and unfairly prejudicial. *See* Fed. R. Evid. 403.

For all the foregoing reasons, Petitioner respectfully requests the Board grant Petitioner's motion to exclude certain cross-examination testimony from Dr. Fudin and strike the portions of Patent Owner's Response that make reference to it.

June 23, 2016

Respectfully Submitted,

/Sarah E. Spires/

Sarah E. Spires (Reg. No. 61,501)
SKIERMONT DERBY LLP
2200 Ross Ave., Ste. 4800W
Dallas, Texas 75201
P: 214-978-6600/F: 214-978-6601
Lead Counsel for Petitioner

Dr. Parvathi Kota (Reg. No. 65,122)
Paul J. Skiermont (*pro hac vice*)
Sadaf R. Abdullah (*pro hac vice*)
SKIERMONT DERBY LLP
2200 Ross Ave., Ste. 4800W
Dallas, Texas 75201
P: 214-978-6600/F: 214-978-6621
Back-Up Counsel for Petitioner

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