

Coalition for Affordable Drugs II LLC

Petitioner

v.

NPS Pharmaceuticals, Inc.

Patent Owner

IPR2015-00990 & IPR2015-01093

U.S. Patent No. 7,056,886

**Patent Owner's Demonstratives
for June 23, 2016, Oral Argument**

§ 103 cannot bar patentability when the invention “is more than the **PREDICTABLE** use of prior art elements according to their established functions.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Peptide formulation is a HIGHLY UNPREDICTABLE ART.

“each molecule has its own unique physical and chemical properties which determine *in vitro* stability. The formulation scientist must also be concerned about the *in vivo* stability of the drug. Thus, the development of successful formulations is dependent upon the ability to study both the *in vitro* and *in vivo* characteristics of the drug as well as its intended application.”

(PO Resp., 24-27; Ex. 1024, 2 (Cleland); Carpenter Dec., ¶¶ 66-68; Ob. of Palmieri, No. 14)

Peptide \neq Protein (PO Resp., 27; Palmieri Ob. 16, 30)

Peptide \neq Small Molecule (PO Resp., 10, 27)

Glucagon \neq GLP-2 or analogs (PO Resp., 43-48)

Serendipity \neq Predictability (PO Resp., 48)

What matters is the path that the person of ordinary skill in the art would have followed. *Otsuka Pharmaceutical Co., Ltd. V. Sandoz, Inc.*, 687 F.3d 1280 (Fed. Cir. 2012)

The parties agree that the person of ordinary skill in the art has knowledge in formulating peptides. (Pet., 21; PO Resp., 24)

Peptide formulators study these primary physical and chemical properties of the subject peptide: (PO Resp., 19-20, 25-26; Carpenter Dec., ¶¶ 68-71, 87, 88)

pH (PO Ob. of Dr. Palmieri, No. 26; Carpenter Dec., ¶¶ 87, 88);

solubility (PO Ob. of Dr. Palmieri, No. 29; Carpenter Dec., ¶¶ 87, 88);

degradation pathways (trriage) (PO Ob. of Dr. Palmieri, No. 9; Carpenter Dec., ¶¶ 87, 88).

Petitioner did not consider any of these properties. (PO Resp., 3, 6, 14, 15, 28-30)

They all differ for glucagon v. GLP-2 = Unpredictability
(PO Resp., 43-48)

POSA would have expected Petitioner's application of the prior art to be **unpredictable.**

(PO Resp., 4-7)

No reasonable expectation of success because glucagon and GLP-2 are so **different.**

(PO Resp., 4-7)

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