

Served on behalf of: Par Pharmaceutical, Inc. et al.

Entered: January 31, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., BRECKENRIDGE PHARMACEUTICAL,
INC., AND ROXANE LABORATORIES, INC.

Petitioners

v.

NOVARTIS AG

Patent Owner

Case IPR2016-00084¹
U.S. Patent No. 5,665,772

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

**PETITIONERS' OBJECTIONS TO
PATENT OWNER'S DEMONSTRATIVES**

¹ Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

IPR2016-00084

U.S. Patent No. 5,665,772

Pursuant to the Board's January 17, 2017 Order, and after a meet and confer held on January 30, 2017, Petitioners hereby file their objections to Patent Owner's demonstratives on the grounds set forth below.

I. Slide 6

A. New argument

Petitioners object to this slide as presenting new argument regarding enthalpy because it goes beyond Patent Owner's argument at POR 25, the only page mentioning enthalpy.

ΔG	=	ΔH	-	T	x	ΔS
Free Energy Change		Enthalpy Change		Temperature		Entropy Change

(PO Slide 6)

B. Reliance on improper observation

Petitioners' further object to Patent Owner's reliance on Ex. 2222 at 113:19-115:6 because it was cited only in an improper observation as explained in Petitioners' response to Patent Owner's Observations 3-4 (impermissibly characterizes testimony, and with similar observations, adds three pages of new argument) (Paper 58).

Ex. 2222 at 113:19-115:6;

(PO Slide 6).

II. Slide 11

A. New argument

Petitioners object to the entire slide as presenting new argument regarding enthalpy because it goes beyond Patent Owner's argument at POR 25, the only page mentioning enthalpy.

The slide has a blue header with the title "Yalkowsky Does Not Discuss Enthalpy" and a subtitle "Paper 27 at 17-18, 25; Paper 55 at 2-3". The main content is on a yellow background and consists of two sections of text:

Dr. Jorgensen:
"Q. So Yalkowsky 1979 is not stating that entropy of fusion can be used to predict water solubility?
"A. Yalkowsky -- **that is correct.** . . . **This is only addressing the entropy change** here. And that's all I was addressing on the flexible side chain issue. So it's a component of predicting it.
"Q. But it's not sufficient?
"A. **It's not the whole ballgame.**"

Dr. Jorgensen:
"Q. Does **Yalkowsky** discuss the impact of adding flexible groups on **enthalpy**?
"A. **Enthalpy, no.** . . . Yalkowsky focused here on **entropy** issues."

(PO Slide 11)

B. Reliance on improper observation

Petitioners further object to Patent Owner's reliance on Ex. 2222 at 120:4-9 because it was cited only in an improper observation as explained in Petitioners' response to Patent Owner's Observations 5 (impermissibly characterizes testimony, and with similar observations, adds three pages of new argument).

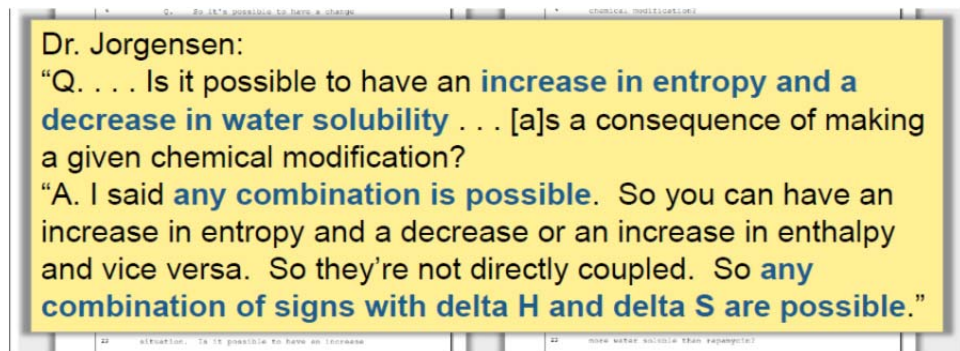
Ex. 2222 at 120:4-9;

(PO Slide 11)

III. Slide 12

A. New Argument

Petitioners object to this slide as presenting new argument regarding enthalpy because it goes beyond Patent Owner's argument at POR 25, the only page mentioning enthalpy (also called delta H).



(PO Slide 12)

B. New citation and improper observation

Petitioners further object to Patent Owner's reliance on Ex. 2222 at 121:22-122:10 (quotation shown above, citation follows) because it was not specifically identified in the motion for observations, but was at best included with an improper observation explained in Petitioners' response to Patent Owner's Observations 4-5 (impermissibly characterizes testimony, and with similar observations, adds three pages of new argument). Patent Owner's Observations 4-5.

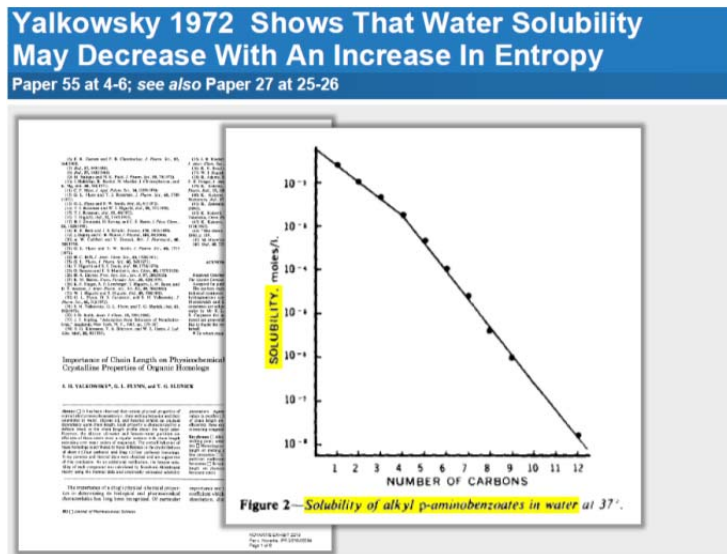
Ex. 2222 at 121:22-122:10; s

(PO Slide 12)

IV. Slide 14

A. New evidence and argument introduced after the Patent Owner's Response

Petitioners object to this entire slide as presenting new evidence (Ex. 2219) and new argument regarding that evidence that should have been included in the Patent Owner's Response.



B. Reliance on improper observation

Petitioners' further object to Patent Owner's reliance on Ex. 2222 at 133:7-134:11 because it was cited only in an improper observation as explained in Petitioners' response to Patent Owner's Observations 8 (impermissibly characterizes testimony, adds new argument).

Ex. 2222 at 133:7-134:11

(PO Slide 14)

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