UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUYE PHARMA GROUP LTD., LUYE PHARMA (USA) LT SHANDONG LUYE PHARMACEUTICAL CO., LTD., and NANJ:

PHARMACEUTICAL CO., LTD.,

Petitioners,

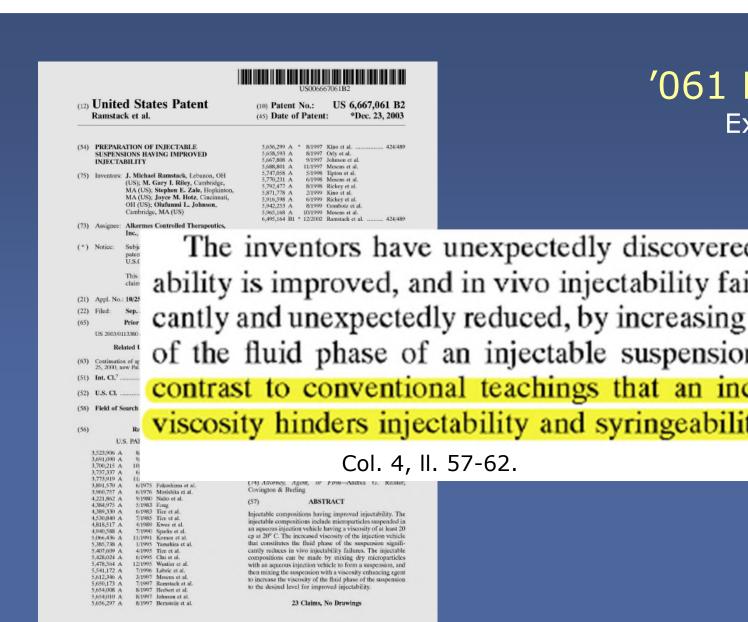
V.

ALKERMES PHARMA IRELAND LTD and ALKERMES CONT
THERAPEUTICS, INC.,
Patent Owners.

Case IPR2016-01096 U.S. Patent No. 6,667,061

PATENT OWNERS' DEMONSTRATIVES ORAL HEARING – AUGUST 28, 2017





Decision (Paper 13) at 3; Patent Owners' Response, 5-6, 8, 32, 39, 41; Exh.

IPR of Patent No. 6,667,0

LUYE1001



POSA Did Not Want to Increase Vis



DeLuca 1st Dep. Tr. Exh. 2016 at 97:10-13

"... A particle in water's going to so pretty fast. In honey, it's going to tall long time. But it would be difficult to the honey over water."

Petitioners' Reply (Paper 40) at 5-6 Evh 1024 at ¶ 21



TEST EXAMPLE 1

Each of the bromperidol-containing microsphere preparations obtained in Examples 1 to 3 was suspended in physiological saline and administered into the femoral muscle of male SD rats (15 weeks of age) in a dose of 12.5 mg as bromperidol. After a predetermined period of time, SUSTAINE PROCESS microspheres which remained in the administered area were periodically recovered to measure remaining amount of bromperidol. As the result, release of the drug at an almost constant rate was confirmed as shown in FIG. 1.

[63] Confinuation-in-part of PCT/IP93/01673, Nov. 15, 1993. U.S. PATENT DOCUMENTS 3,773,919 11/1973 Boswell et al. 4 Claims, 4 Drawing Sheets 120-● EXAMPLE I

United S

[73] Assignee: 1

[21] Appl. No.: 4 [22] Filed: 1

TEST EXAMPLE 4

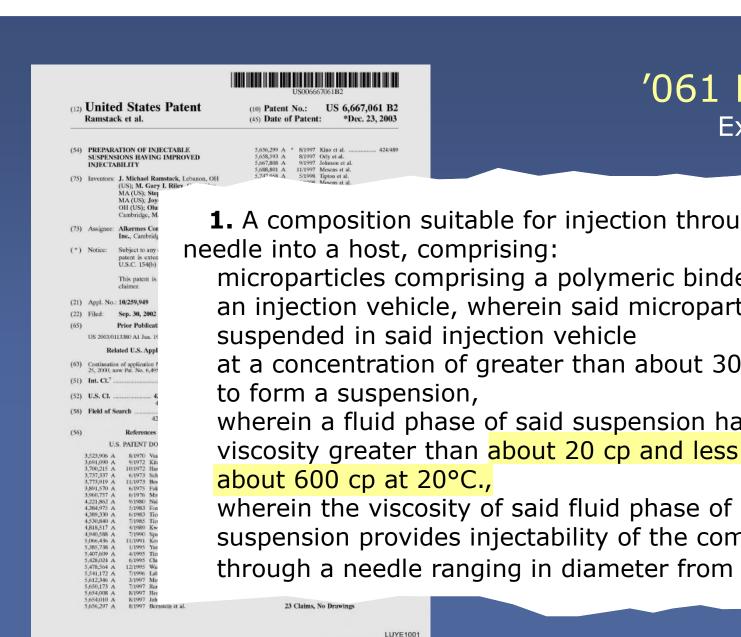
A 15 mg portion of each of the haloperidol-containing microsphere preparations obtained from the following Formulations C and D was dispersed in 20 ml of physiological saline and shaken at 37° C. and at 80 revolutions per minute using a constant temperature shaker (manufactured by Taitech), and samples were periodically collected to calculate drug releasing ratio by ultraviolet absorption photometry (245 nm). As shown in the FIG. 4, it was confirmed that the microsphere preparation of Formulation C which comprises finely ground haloperidol can release the drug at a rate of almost 0 order.

TEST EXAM

A 25 mg portion of each of the microsphere preparations obtained mulations A and B was dispersed saline and shaken at 37° C, and at using a constant temperature Yamato Kagaku). Thereafter, sa collected to calculate drug rele absorption photometry (245 nm). confirmed that the microsphere p A which comprises finely ground the drug at a rate of almost 0 or

Patent Owners' Response (Paper 33) at 11; Exh. 2014 at ¶¶ 83-84; Exh. 208





Decision (Paner 13) at 4: Patent Owners' Response (Paner 33) at 5



IPR of Patent No. 6,667,0

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