

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* DEEPAK K. THASSU,  
Appellant

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Appeal 2008-3530  
Application 10/223,291<sup>1</sup>  
Technology Center 1600

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Decided: June 5, 2008

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Before ADRIENE LEPIANE HANLON, CAROL A. SPIEGEL, and  
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

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<sup>1</sup> Application 10/223,291 ("the 291 application") was filed 19 August 2002. The real party in interest is said to be L. Perrigo Company (Appeal Brief, filed 18 September 2007 ("App. Br."), 2.

I. Statement of the Case

This is an appeal under 35 U.S.C. § 134 (2002) from a final rejection of claims 1-6 and 10. Claims 7-9 and 11-33, the only other pending claims, are withdrawn from consideration (App. Br. 2; Ans.<sup>2</sup> 2). We have jurisdiction under 35 U.S.C. § 6(b) (2002). We REVERSE.

The dissolution rate of a particulate drug can vary with the particle size distribution of the active drug particles in a pharmaceutical formulation (Spec.<sup>3</sup> 1:12-28). The subject matter on appeal is directed to a method of obtaining active particles of a single desired particle size range from a raw source of pharmaceutically active particles which tend to agglomerate (*id.*). The claimed method processes the raw source through a first screen supplied with ultrasonic energy to break up agglomerates and sized to remove particles that are too large and then through a second screen sized to remove particles that are too small (Spec. 3:22-4:9). The active drug particles retained on the second screen are used to make the final pharmaceutical drug formulation and are said to have a monomodal particle size distribution (Spec. 4:9-20). Claim 1 is illustrative and reads (App. Br. App'x of Claims 1, emphasis added):

1. A method of obtaining pharmaceutically active particles having a desired monomodal particle size distribution, comprising:

positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size;

placing pharmaceutically active particles on said first screen; and

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<sup>2</sup> Examiner's Answer mailed 12 December 2007 ("Ans.").

<sup>3</sup> Specification of the 291 application ("Spec.").

propagating ultrasonic energy to said pharmaceutically active particles on said first screen while said first screen is located above said second screen, whereby, the ultrasonic energy causes agglomerates of smaller particles held together by electrostatic attraction to become de-agglomerated, and active particles having a true monomodal particle size distribution are retained on the second screen.

The Examiner relies on the following references<sup>4</sup> of record as evidence of unpatentability:

Pitchford	3,167,259	Jan. 26, 1965
Liversidge	5,145,684	Sep. 8, 1992
Baichwal	5,472,711	Dec. 5, 1995
McCurdy	5,520,932	May 28, 1996

The Examiner has rejected (i) claims 1-6 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of McCurdy, Pitchford, and Liversidge and (ii) claim 10 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of McCurdy, Liversidge, and Baichwal (FR<sup>5</sup> 2 and 8; Ans. 3).

The dispositive issue is whether the Examiner reversibly erred in failing to find all limitations of the claimed invention in the prior art. Specifically, the issue is whether the combined teachings of Pitchford, Liversidge, Baichwal and/or McCurdy disclose or suggest "positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size," as required by all the claims on appeal.

Findings of fact set forth in this opinion are supported by a preponderance of the evidence of record.

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<sup>4</sup> No references to *et al.* are made in this opinion.

<sup>5</sup> Final Rejection mailed 26 March 2007 ("FR").

## II. Discussion

A claimed invention is not patentable if it would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Facts relevant to a determination of obviousness include (1) scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) relevant objective evidence of obviousness or non-obviousness. *KSR*, 127 S.Ct. at 1734; *Graham*, 383 U.S. at 17. All limitations of the claimed invention must be taught or suggested by the prior art to establish *prima facie* obviousness. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

McCurdy discloses a method for obtaining "fine-milled" colestipol hydrochloride ("FMCH") by wet milling colestipol hydrochloride with a Comitrol 1700 mill configured with a 222084 microcut head, drying the wet milled drug, and then sizing it with various equipment to yield either a bi-modal mixture of particle aggregates and primary particles or a uni-modal mixture of discrete primary particles (McCurdy abstract; 3:15-17 and 27-31; 6:1-7). According to McCurdy, aggregates of FMCH may be broken up with a mill with an impact mechanism of size reduction, a Bantom Mikropulverizer using a 0.046 HB screen to produce a new particle size distribution, or a precise incremental cutting machine, such as the Comitrol 1700 (*id.* at 6:43-46; 8:38-48).

The Examiner acknowledges that McCurdy does not disclose first and second screens (Ans. 6). Hence, McCurdy fails to disclose or suggest "positioning a first screen having a selected mesh aperture size above a

second screen having a selected *smaller* mesh aperture size" as required by the claimed method.

Pitchford discloses an apparatus for grinding materials to a selective and uniform particle size (Pitchford 1:9-13; 2:21-24). The apparatus comprises (i) a grinding/blending chamber for receiving the material to be processed, (ii) spaced particle separating means, such as screens arranged at opposite ends or sides of the chamber, designed to permit passage of particles of a predetermined size, and (iii) a collecting means for receiving particles passing through the particle separating means (*id.* at 2:37-47). A fluid, preferably air, for carrying particles to and away from the spaced separating means is alternatively pulsed through the chamber through one screen and out the other (*id.* at 2:47-51). "In the pulsing cycle, air goes in through the screen at one end of the chamber, cleaning this screen on the way in; continues through the chamber and blasts the powder against the screen at the opposite end of the chamber; finally passing onto a collector" (*id.* at 2:51-55). The second pulse in the cycle reverses the air flow, "thereby blasting powder against the previously cleaned screen while cleaning the screen against which powder was blasted by the previous pulse" (*id.* at 2:60-3:1).

The Examiner does not point out, and we do not find, where Pitchford discloses or suggests "positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size" as required by the claimed method. The Examiner contends that Pitchford suggests the claim limitation at issue because "Pitchford teaches that his screens are adapted to permit the passage of particles of a predetermined particle size" (Ans. 12). However, as pointed out by the

Appellant (App. Br. 8), the Pitchford apparatus is using screens of the *same* size by virtue of their alternating use in separating particles of the predetermined size.

Liversidge discloses preparing nanosized drug particles that do not appreciably flocculate or agglomerate by wet milling in the presence of grinding media in conjunction with a surface modifier (Liversidge 3:16-24). Useful surface modifiers include those which physically adhere to, but not chemically bond to, the surface of the drug particles (*id.* at 4:30-33). The surface modifiers are believed to sterically hinder or electrostatically repel flocculation and/or agglomeration of the drug particles (*id.*, 8:21-29). Compatible pairs of drug particles and surface modifiers can be selected by (a) dispersing coarse particles of a selected drug in a liquid in which the drug is insoluble, (b) wet milling the dispersion, (c) dividing milled material into aliquots, (d) adding surface modifiers in different amounts to each of the aliquots, (e) sonicating to disperse agglomerates, and (f) analyzing to identify those surface modifiers and amounts that provide a stable dispersion (*id.* at 7:21-46). In some embodiments, Liversidge discloses using a single screen to separate a slurry of drug particles and liquid medium from glass grinding media (*id.* see e.g., 9:47-51 and 10:56-59).

The Examiner does not point out, and we do not find, where Liversidge discloses or suggests "positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size" as required by the claimed method.

Baichwal discloses a method of preparing a pharmaceutical formulation providing a multiphasic release of a therapeutically active drug when the formulation is exposed to aqueous or gastric fluid (Baichwal 4:40-

57). Baichwal does not disclose or suggest "positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size" as required by the claimed method. Indeed, the Examiner relied on Baichwal solely for its disclosure of acetaminophen as a therapeutically, i.e., pharmaceutically, active drug (Ans. 17-18).

Since neither McCurdy, Pitchford, Liversidge, nor Baichwal disclose or suggest "positioning a first screen having a selected mesh aperture size above a second screen having a selected *smaller* mesh aperture size" as required by the claimed method, the Examiner has failed to establish a sufficient factual basis to support a conclusion of *prima facie* obviousness. Consequently, we reverse the rejections of (i) claims 1-6 under § 103(a) as unpatentable over McCurdy, Pitchford, and Liversidge and (ii) claim 10 under § 103(a) as unpatentable over McCurdy, Liversidge, and Baichwal.

It is not necessary to reach other arguments that the applied prior art also fails to teach or suggest other limitations recited in claim 1.

### III. Order

Upon consideration of the record, and for the reasons given, it is ORDERED that the Examiner's decision to reject claims 1-6 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of McCurdy, Pitchford, and Liversidge is REVERSED, and

FURTHER ORDERED that the Examiner's decision to reject claim 10 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of McCurdy, Liversidge, and Baichwal is REVERSED.

REVERSED

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