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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN HILFINGER, JAE SEUNG KIM, and PAUL KIJEK

Appeal 2011-003275
Application 11/097,487
Technology Center 1600

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and JOHN G. NEW,
Administrative Patent Judges.

FRANKLIN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a pharmaceutical composition and a method of making a pharmaceutical composition comprising a release control agent. The Patent Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The invention concerns “pharmaceutical dosage forms that increase the solubility of water insoluble drugs and also control the release rates of

such dosage forms for the extended delivery of pharmaceuticals.” (Spec. 1, ll. 8-10.)

Claims 1-11 and 13-27 are on appeal. Claims 1 and 14 are representative and read as follows:

1. A pharmaceutical composition comprising:
 - a pharmaceutical ingredient in the form of a powder or granule;
 - a water soluble high molecular weight excipient of molecular weight between 1,000 and 1,000,000 Daltons;
 - a water insoluble hydrophilic amphiphilic excipient, wherein said pharmaceutical ingredient, said water soluble high molecular weight excipient, and said water insoluble hydrophilic amphiphilic excipient are solution mixed and dried to form a modified pharmaceutical ingredient in simultaneous contact with both said water soluble high molecular weight excipient and said water insoluble hydrophilic amphiphilic excipient; and
 - a release control agent compacted about said modified pharmaceutical ingredient and present at levels from 1 to 40 total weight percent.

14. A method of making a pharmaceutical composition comprising:
 - coating at least one pharmaceutical ingredient with a mixture consisting essentially of a water soluble high molecular weight polymer of molecular weight between 1,000 and 1,000,000 Daltons and a water insoluble amphiphilic component in solution to form a modified pharmaceutical ingredient;
 - drying said modified pharmaceutical ingredient; and
 - contacting the dry modified pharmaceutical ingredient with a release control component present from 1 to 40 total weight percent where said release control agent is selected from the group consisting of: glyceryl palmitostearate, alpha-starch, gum arabic, hydroxypropylcellulose, carboxymethylcellulose, polyvinylpyrrolidone, acrylic copolymers, acrylate/alkylacrylate copolymers, polyacrylamides, polysaccharides, hydroxypropylmethylcellulose, natural gums and clays, lipophilic gelling agents, modified clays, bentones, fatty acid metal salts, aluminum stearates, hydrophobic silica, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, hydroxyethyl cellulose, polyethylenes, ethylcellulose, and a PEG of appropriate molecular weight.

The Examiner rejected the claims as follows:

- claims 1-3, 5-10, 14, 15, 17, 18, and 23-27 under 35 U.S.C. § 103(a) as unpatentable over Amidon¹ and Mehta;²
- claims 1-3, 5-11, 13-18, and 20-27 under 35 U.S.C. § 103(a) as unpatentable over Amidon, Mehta, and Ullah;³
- claims 1-10, 14, 15, and 17-27 under 35 U.S.C. § 103(a) as unpatentable over Amidon, Mehta, and Zenter.⁴

OBVIOUSNESS

The Examiner's position is that Amidon taught methods of increasing the solubility of poorly soluble drugs and compositions made by such methods. (Ans. 3.) The Examiner found that Amidon's methods included: dissolving gelatin, a water soluble high molecular weight excipient, in water; adding lecithin, a water insoluble hydrophilic amphiphilic excipient; slowly adding a pharmaceutical ingredient in powdered or granular form causing a uniform coating (compacting) of gelatin/lecithin on the pharmaceutical; drying the composition; forming the dried coated particles into tablets. (*Id.* 3-4.) However, the Examiner found that Amidon did not disclose a release control agent compacted about the modified pharmaceutical ingredient. (*Id.* at 4.)

The Examiner found that Mehta taught methods of tabulating coated pellets and specifically taught that it was desirable to add an inert diluent,

¹ US Patent No. 5,851,275 issued to Gordon L. Amidon et al., Dec. 22, 1998.

² US Patent No. 5,871,776 issued to Atul M. Mehta, Feb. 16, 1999.

³ US Patent No. 6,235,311 B1 issued to Ismat Ulla et al., May 22, 2001.

⁴ US Patent No. 4,994,273 issued to Gaylen M. Zentner et al., Feb. 19, 1991.

such as glyceryl palmitostearate, during tableting, to avoid rupturing the pellets during compression. (*Id.*)

According to the Examiner, an artisan of ordinary skill at the time of the invention would have found it obvious to use glyceryl palmitostearate as the inert diluent while tableting the pellets of Amidon. (*Id.*) The Examiner reasoned that the artisan would have understood that using the diluent to cushion the pellets involved mixing the pellets with the diluent and then compressing the mixture in a tablet press, resulting in the glyceryl palmitostearate being “compacted about” the modified pharmaceutical. (*Id.*)

Appellants contend, among other things, that the Examiner’s motivation for combining Amidon and Mehta is not supported by the references. (App. Br. 9-10.) Specifically, Appellants assert that Amidon’s formulation does not require the addition of a cushioning agent during tableting, because Amidon taught that its “powders and granulations [have] excellent flow and compression properties for high speed manufacturing of tablets and capsules.” (*Id.* at 10) (quoting Amidon col. 4, ll. 18-21). According to Appellants, Amidon did not suggest any appreciable risk of pellet rupture such that an artisan would have been motivated to combine a cushioning agent during pelleting of Amidon’s invention. (*Id.*)

We agree with Appellants. Accordingly, we reverse the obviousness rejection of claims 1-3, 5-10, 14, 15, 17, 18, and 23-27 under 35 U.S.C. § 103(a) as unpatentable over Amidon and Mehta.

Because the Examiner relied on the same motivation for combining Amidon and Mehta in the rejection over Amidon, Mehta, and Ullah, as well as the rejection over Amidon, Mehta, and Zentner (*see* Ans. 5-6) we also reverse each of these rejections.

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Application 11/097,487

SUMMARY

We reverse each of the obviousness rejections.

REVERSED

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