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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,878	08/15/2003	Rama Haldar	FDN-2775	2305

7590 02/01/2010

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ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
02/01/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAMA HALDAR, JOHN ZAMORA,
DIPAN B. RAY, WILLIAM DREFKO,
GREB DUBROWNY, and SIDNEY ETIENNE

Appeal 2009-010262
Application 10/641,878
Technology Center 1600

Decided: February 1, 2010

Before LORA M. GREEN, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a binder composition and process for direct compression of poorly compressible drugs into tablets. 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 a process for making tablets of poorly compressible drugs, such as naproxen or acetaminophen, by direct compression, as well as a binder composition for such drugs. (Spec. 1-2). Claims 1, 3-5, 10-12, 14, 16, 17, 22, and 24-29, which are all the pending claims, are on appeal. Independent claims 1, 10, and 14 are representative and read as follows:

1. A process for making tablets of a poorly compressible drug by direct compression, which comprises providing a binder composition which is made by spray drying an aqueous dispersion of a copolymer of polyvinylpyrrolidone (PVP) and vinyl acetate (VA), having a defined glass transition temperature (Tg), and an effective amount of 5-15 wt. % of a plasticizer which is an organic ester or polyol therewith to reduce the Tg of said copolymer by at least 20°C, admixing said binder composition and 50-90 wt. % of said drug, and forming a tablet thereof by direct compression having a predetermined hardness and friability, and at an acceptable compression force.

10. A process according to claim 1 wherein said plasticizer is triethyl citrate.

14. A binder composition for direct compression of a poorly compressible drug, comprising a free-flowing powder which is a spray dried aqueous dispersion of a copolymer of polyvinylpyrrolidone (PVP) and vinyl acetate (VA), and an effective amount of 5-15 wt. % of a plasticizer which is an organic ester or polyol reduce the Tg of the polymer by at least 20°C.

The Examiner rejected the claims as follows:

• claims 1, 3-5, 10-12, 14, 16, 17, 22, and 24-29 under 35 U.S.C. § 103(a) over Upadhyay[1] and Grabowski[2]; and

• claims 1 and 10 under 35 U.S.C. § 103(a) over Upadhyay, Grabowski, and Bai[3].

OBVIOUSNESS

The Issue

The Examiner's position is that Upadhyay taught a tablet making process directly compressing a binder formulation comprising binders such as polyvinylpyrrolidone, vinyl acetate or hydroxypropylcellulose, plasticizers such as polyethylene glycol, and other excipients. (Ans. 23). The Examiner also found that Upadhyay disclosed that the binder composition comprises up to 3% of the plasticizer. (*Id.*). Additionally, the Examiner found that Upadhyay disclosed that the drug acetaminophen is present in the formulation from 80-95%. (*Id.* at 4).

According to the Examiner, the binder of Upadhyay would "have the same defined glass transition temperature [as recited in the claims] since the binding polymers are identical to those of the instant claims." (*Id.*). Also, the Examiner reasoned that "since polyethylene glycol is present in the same concentration in [Upadhyay,] it would necessarily reduce the Tg of the binding copolymer since it [is] identical to useful plasticizers recited in the Specification and is a polyol." (*Id.*).

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[1] Patent Application Publication No. US 2001/0044472 A1 by Ajay Hasmukhlal Upadhyay et al., published Nov. 22, 2001.
[2] US Patent No. 5,684,040 issued to Sven Grabowski et al., Nov. 4, 1997.
[3] US Patent No. 5,840,329 issued to Jane Pei-Fan Bai, Nov. 24, 1998.

Turning to Grabowski, the Examiner found that the reference disclosed a tablet formulation comprising binders including polyvinylpyrrolidone and copolymers of N-vinylpyrrolidone and vinyl acetate, wherein the N-vinylpyrrolidone is present in an amount from 40-70% while the vinyl acetate is present from 3-60%. (*Id.* at 4). The Examiner also found that Grabowski disclosed that the formulation included plasticizers, such as polyethylene glycol, present in an amount from 0.5-15%. (*Id.*) Additionally, the Examiner found that Grabowski disclosed that the composition further comprised lubricants and stabilizers. (*Id.* at 5). According to the Examiner, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the binder and plasticizers of Grabowski in Upadhyay's process to improve stability of the formulated tablet. (*Id.*).

Appellants contend that the Examiner failed to establish a prima facie case of obviousness, alleging that the Examiner has not provided sufficient motivation for combining the references. (App. Br. 10; Reply Br. 7). Regarding the separate rejection of claims 1 and 10, Appellants assert that Bai "fails to remedy the shortcomings of the other references and, therefore, fails to provide the necessary disclosure to establish a *prima facie* case of obviousness with respect to the pending claims." (App. Br. 11).

The issue with respect to the rejections is whether the Examiner provided a reason as to why the ordinary artisan would have combined the references as set forth in the rejections.

Findings of Fact

1. Upadhyay disclosed an acetaminophen drug composition that is directly compressible into a tablet dosage form. (Upadhyay, Abstract).
2. Upadhyay disclosed the composition comprises a lubricant, such as polyethylene glycol, from 0.3 to 3 weight percent. (*Id.* at [0012], [0022]).
3. Upadhyay disclosed that "[a]ny pharmaceutically acceptable compound capable of rendering the acetaminophen particles compactable is suitable as the binder compound of the composition," such as polyvinylpyrrolidones. (*Id.* at [0018]).
4. Grabowski disclosed drug compositions comprising at least one water-soluble polymer, such as "polyvinylpyrrolidone and N-vinylpyrrolidone/vinyl acetate copolymers, especially polyvinylpyrrolidone and copolymers of 40-70% by weight of N-vinylpyrrolidone and 30-60% by weight of vinyl acetate." (Grabowski 3:8-13).
5. Grabowski disclosed that the compositions of the invention may also contain conventional pharmaceutical ancillary substances such as fillers, lubricants, plasticizers, dyes and stabilizers. (*Id.* at 3:56-60).
6. Grabowski disclosed that examples of such plasticizers include polyethylene glycol, in an amount of about 0.5 to 15% by weight. (*Id.* at 4:6-13).
7. Bai disclosed a drug delivery system comprising a binder composition and plasticizers, such as polyethylene glycol and triethyl citrate. (Bai Abstract; 7:65).

Principles of Law

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). A rejection for obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Analysis

In rejecting the instant claims as obvious over Upadhyay and Grabowski, the Examiner combined Grabowski's co-polymer binder and plasticizer in Upadhyay's process for making tablets by direct compression. (Ans. 3-5). The Examiner reasoned that one of ordinary skill in the art at the time the invention was made would have been motivated to do so "in order to improve stability." (*Id.* at 5). Appellants assert that the Examiner's reasoning is not supported by the prior art because Grabowski does not provide any "indication or suggestion that the incorporation of … the particular binder would somehow improve stability of the composition." (Reply Br. 7).

We agree with Appellants. The Examiner has neither identified any objective teaching in the prior art, nor referenced knowledge generally available to one of ordinary skill in the art that would have led that individual to combine "the binder and plasticizers of [Upadhyay] into the process of [Grabowski] in order to improve stability." (*See* Ans. 5). Moreover, the Examiner has not provided any reasoning why stability was a

problem that needed to be solved. Grabowski did not teach that its binders or plasticizers improve the stability of the disclosed composition. Nor did Grabowski suggest that the stability of its composition was problematic. Rather, Grabowski specifically taught that *stabilizers* may be added to the compositions of the invention. (FF5). Thus, Grabowski provided a means other than the binders and plasticizers for stabilizing the composition. Consequently, we conclude that this record does not include sufficient evidence to support the obviousness rejection.

In the rejection of claims 1 and 10 as obvious over Upadhyay, Grabowski and Bai, the Examiner relied upon the same evidence for combining Grabowski's binder in Upadhyay's direct compression tableting process, i.e., to improve stability. (*See* Ans. 5-6). For the same reasons discussed above, we conclude the evidence is insufficient to support the obviousness rejection.

CONCLUSIONS OF LAW

Appellants have demonstrated that the evidence was insufficient to support a prima facie case of obviousness.

SUMMARY

We reverse the rejection of claims 1, 3-5, 10-12, 14, 16, 17, 22, and 24-29 under 35 U.S.C. § 103(a) as obvious over Upadhyay and Grabowski; and

we reverse the rejection of claims 1 and 10 under 35 U.S.C. § 103(a) as obvious under Upadhyay, Grabowski and Bai.

REVERSED

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