

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* STEPHAN HAUSMANN, THOMAS KIY,  
IVAN TOMKA, and ROLF MULLER

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Appeal 2008-3512  
Application 10/416,073  
Technology Center 1600

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Decided: June 30, 2008

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Before ERIC GRIMES, LORA M. GREEN, and  
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the  
Examiner's final rejection of claims 16 and 18-31. We have jurisdiction

under 35 U.S.C. § 6(b). Claim 16<sup>1</sup> is representative of the claims on appeal, and reads as follows:

16. A process for producing a protein-free soft capsule casing a gel of a starch mixture and a swelling agent, where the starch mixture comprises at least one starch component which has a reduced degree of branching compared with a native starch, and where at least one of the starch components has a DP(N) of > 100, in which process said starch mixture and swelling agent are homogenized at temperatures > 160°C, the gel produced is thermoformed in a suitable processing method to give a sheet, a film or a strip, and the soft capsule is then produced by the rotary die process.

The Examiner relies on the following references:

Bengs	US 6,323,265 B1	Nov. 27, 2001
Stroud	WO 9209274	Jun. 11, 1992

We reverse.

## DISCUSSION

Claims 16 and 18-31 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Bengs and Stroud.

Bengs is cited for teaching “a thermoplastic mixture for producing biodegradable moldings,” including capsules (Ans. 3). According to the Examiner, the mixture “comprises (a) 100 parts by weight of a biocatalytically produced 1,4- $\alpha$ -D-polyglucans, (b) up to 400 parts by weight of a melt-processable polymeric material different from A, (c) plasticizer, (d) up to 10 parts by weight water, and (e) other additives.” (*Id.*) Bengs is also cited for teaching that the ingredients may be mixed at a temperature

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<sup>1</sup> We note that claims 20-22 depend from claim 1, but claim 1 has been cancelled (App. Br. 3). We thus assume that the recitation of claim 1 is a typographical error, and that the claims should read as depending from claim 16.

from 100 to 160°C (*id.* at 4). The Examiner notes that “Bengs does not explicitly teach the capsule is a soft capsule, and the process for producing soft capsule by rotary die.” (Ans. 4.)

Stroud is cited for teaching “a process for producing a soft capsule comprising the steps of mixing starches, water, and other ingredients, heating and blending until a homogenous mixture is obtained, and producing capsule by the rotary-die.” (*Id.*)

The Examiner concludes:

Thus, it would have been obvious for one of ordinary skill in the art to prepare a soft starch capsule in view of the teachings of Bengs and Stroud to obtain the claimed invention, because Bengs teaches reproducible moldings and sheets can be produced from starch mixtures, and because Stroud teaches the capsules using starch having high amylase content form strong seals, resistant to changes in shape, and more economical to manufacture (see abstract).

(*Id.*)

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). In order to determine whether a *prima facie* case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present. In order to facilitate review of the obviousness determination, the “analysis

should be made explicit.” *KSR International Co., v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

Appellants argue that “only Stroud . . . teaches or suggests soft capsules or a method of producing a capsule,” that Stroud “only teaches soft capsules which contain gelatin,” and if “the capsules contain gelatin they are not protein free.” (App. Br. 12.) Moreover, according to Appellants, there “exists no reason in Stroud to believe that the capsules could be made without gelatin” (*id.*), and as Bengs teaches that protein or gelatin can be added (*id.* at 9), the combination of references does not teach or suggest a process for producing protein-free soft capsules as set forth in independent claim 16 (*see, e.g., id.* at 9-10).

As noted by the Examiner, Bengs teaches a thermoplastic mixture for producing moldings, wherein the mixture comprises (a) 100 parts by weight of a biocatalytically produced 1,4- $\alpha$ -D-polyglucans, (b) up to 400 parts by weight of a melt-processable polymeric material different from A, (c) plasticizer, (d) up to 10 parts by weight water, and (e) other additives (Ans. 3). One of the additives taught by Bengs, however, is protein, such as gelatin, vegetable protein, egg yolk, egg white, or the like (Bengs, col. 5, l. 54-col. 6, l. 2). The amount of protein added may be 2-40% by weight, preferably 3-10% by weight (*id.* at col. 12, ll. 43-46).

We also agree with the Examiner that Bengs teaches the formation of capsules. Specifically, what Bengs teaches is that “the products according to the invention cover a large number of possible applications,” including “moldings produced by injection molding, especially . . . capsules, . . . release-slowing materials for controlled release of active ingredients in general, especially drugs.” (Bengs, col. 11, ll. 26-36.) According to Bengs,

it “is moreover possible for the active substance to be released from films, sheets, tablets, particles, microparticles, rods, or other extrudates or other moldings.” (*Id.* at ll. 36-38). The tablets for controlled release may be coated tablets (*id.* at ll. 62-65). Bengs, however, does not teach the formation of soft capsules, nor does Bengs teach the use of a rotary die process.

Stroud teaches that soft gelatin capsules comprising mainly gelatin, glycerol and water are desirable dosage forms for the administration of many therapeutic substances (Stroud, p. 1, ll. 8-11). The gelatin shell is readily soluble in the stomach, and the contents are readily absorbed due to the absence of excipients usually present in other oral dosage forms such as tablets and pills (*id.* at ll. 12-14). Stroud further teaches a process of preparing a soft capsule in which high amylase starch is added to a solution of gelatin, glycerin, and water, wherein the mixture is heated and blended until a homogenous mixture is obtained, and then used to prepare soft gelatin capsules by the rotary-die encapsulation process (Stroud, p. 5, ll. 23-27). Stroud teaches that the high amylase starch may be used to replace as much as 85% of the gelatin used in the formation of the capsule, which results in a cost saving (p. 4, ll. 9-18). All of the capsules of Stroud, however, contain some amount of gelatin (p. 5, Table 1; *see also* p. 7, Example 4).

Given Stroud’s teaching that it is desirable to reduce the amount of gelatin in a soft capsule, but that all the capsules contain a certain amount of gelatin (i.e., protein) with the starch, and Bengs’ teaching that one can add gelatin to the thermoplastic mixtures taught by that reference, we conclude that Appellants have the better argument, and that the references as

combined do not teach or suggest a method of producing a protein free soft capsule as claimed, and the rejection is reversed.

The Examiner argues that Examples 16, 17, and 19 of Bengs show that “the components for making film or thermoplastic sheets do not require protein.” (Ans. 5) Examples 16 and 17 of Bengs are drawn to the production of extruded sheets, and Example 19 is drawn to the production of blown films. The product formed in Example 16 is initially flexible, but solidifies in the air (Bengs, col. 18, ll. 11-21), and thus does not appear to be suitable for soft capsules and the Examiner provides no evidence that it is. The products of Examples 18 and 19, on the other hand, may be wound into sheets, but the Examiner has not provided any scientific reasoning or evidence as to how those methods are predictive of the results that would be obtained using the mixtures to produce soft capsules using a rotary die process.

The Examiner argues further that the Specification “defines ‘protein-free capsule’ as capsule without animal proteins, or which consist of raw materials which are not based on animal sources.” (Ans. 5, citing Specification ¶ 0003.) According to the Examiner, the “present invention provides capsules that are free of animal protein which comply with ‘kosher’ and ‘halal’ requirements,” and that the proteins taught by Bengs include vegetable protein, thus “it is obvious that the capsule taught by Bengs does not contain animal protein as required by the present invention, and thus, meet the requirements desired by the present invention, namely, capsules that comply with ‘kosher’ or ‘halal’ requirements.” (Ans. 5-6.)

Again, the Examiner’s argument is not convincing. The portion of the Specification relied upon by the Examiner is background, discussing the

need for soft capsules which consist of raw materials that are not based on animal sources (Specification ¶ 0003), and is not a definition of the term “protein-free.” Moreover, the Examples in the Specification are all drawn to soft capsules made from a mixture of starch, glycerol, and water (Specification 17-19), and thus the ordinary artisan would interpret “protein-free” as used in the claim as not having protein at all, including vegetable protein. *See, e.g., In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (noting that during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art).

#### CONCLUSION

Because we conclude that the Examiner has not set forth a *prima facie* case that claims 16 and 18-31 are obvious over the combination of Bengs and Stroud, the rejection is reversed.

REVERSED

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